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Icad Inc (ICAD-NASDAQ)

ICAD: Q2 Results - Therapy Biz Booming, Dip in Detection

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	07/29/2011
Current Price (07/31/13)	$5.70
Target Price	**$7.80**

OUTLOOK

iCAD goes into 2013 with a tailwind behind both its Therapy and Detection business segments. Therapy growth should come from substantially improved reimbursement for breast IORT, solid and growing demand for non-melanoma skin cancer, entry into cervical cancer and greater awareness (to the clinical as well as patient communities) of the benefits of IORT therapy over traditional surgery and radiation. The Detection segment looks promising to return to long-term growth aided by iCAD's recent strategy shift towards a greater reliance on recurring revenue, services and a conventional software business model, new product launches, and a recently announced development agreement with Invivo (part of Philips Healthcare).

This coupled with a stringent focus on cost control could mark an important inflection point for iCAD.

We are maintaining our Outperform rating. Our price target is $7.80/share.

SUMMARY DATA

52-Week High	**$6.90**
52-Week Low	**$1.85**
One-Year Return (%)	**187.88**
Beta	**1.39**
Average Daily Volume (sh)	**31,184**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$62**
Short Interest Ratio (days)	**3.43**
Institutional Ownership (%)	**16**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-5.1**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2013 Estimate	**N/A**
P/E using 2014 Estimate	**285**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**Small-Blend**
Industry	**Comp-Software**

ZACKS ESTIMATES

Revenue
(in '000 of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	6,343 A	5,931 A	8,183 A	7,818 A	28,275 A
2013	7,930 A	7,712 A	8,547 E	9,854 E	34,043 E
2014					49,491 E
2015					74,846 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.21 A	-$0.27 A	-$0.14 A	-$0.25 A	-$0.87 A
2013	-$0.07 A	-$0.17 A	-$0.08 E	-$0.03 E	-$0.36 E
2014					$0.02 E
2015					$0.50 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW…

Q2 2013 RESULTS

iCAD (ICAD) announced financial results for the second quarter ending June 30th. Aside from softness in Cancer Detection revenue as a result of weaker than expected international product sales, results remained generally in-line with our numbers. Total revenue increased by 30% yoy while operating expenses fell better than 6% over the same period, pushing operating income to its highest level since Q4 2009. Management noted that they expect strong revenue performance in the second half of the year with essentially no expected increase in operating expenses.

Importantly, revenue from Cancer Therapy, which is expected to be the major long-term growth driver of the company, continues to show a strong upward growth trend. Demand continues to come from both IORT breast and skin cancer and driven by greater awareness of the benefits of brachytherapy over traditional cancer therapy as well as improved reimbursement. With only low-single digit penetration in these markets as well as additional indications coming on-line in the near-term, including for cervical cancer, coupled with the real potential for even greater reimbursement, we believe iCAD's Therapy business has tremendous upside growth potential. And while Detection international product-related revenue disappointed in Q2, management indicated that subscription based product and service revenue in that segment, where the company recently trained a greater focus in order to capitalize on recurring revenue sources, posted positive growth. We continue to expect the transition to a greater focus on recurring revenue sources to pay dividends over the long term and the 24% increase in Detection service revenue in Q2 (and 14% in Q1) is encouraging in that regard. Detection should also benefit from new product launches - both recent and near-term product introductions.

All indications point to continued revenue growth and management again noted on the call that operating expenses should remain at about the current quarterly level - assuming no deterioration in gross margins (which we do not anticipate, in fact GM should grow over the longer-term with increasing sales of higher margin consumables), positive operating income and sustainable positive operating cash flow should be right around the corner (as we first noted in our previous updates we think ICAD can reach sustainable positive cash flow sometime during the current year and generate positive net income and EPS as soon as 2014).

Revenue
Revenue of $7.7MM was up 30% y-o-y and about 10% lower than our $8.6MM estimate - the difference almost entirely due to lower than expected Detection product-related revenue.

- **Cancer Detection:** $3.8MM actual (-14% yoy) vs. $4.5MM estimate
  - Total product revenue in cancer detection was about $1.6 million, down from about $2.7 million in Q2 2012 and well below our $2.5 million estimate. Management noted that product revenue was particularly, and unexpectedly, weak internationally. This was partially offset by growth in U.S. product sales and continued momentum in services revenue. And despite the weakness in international product sales in Q2, per management's comments on the call, this should rebound in the second half of the year. Relative to services revenue, as a reminder, in 2012 iCAD implemented a shift in strategy to one with a greater focus on services and subscriptions with the goal of leveraging more recurring revenue and higher margins. This appears to be bearing fruit with Detection services revenue growing 22% in Q4 2012, 14% in Q1 2013 and 24% in the most recent quarter. And despite the newly implemented 2.3% medical device tax, iCAD has been able to maintain beefy margins, which we think is a direct benefit of the recent shift towards services/subscriptions.

    We continue to look for the Detection segment to turn the corner to sustained growth. This being fueled by new product launches (PowerLook AMP, CAD for tomosynthesis, etc.), more annual licensing agreements, increased service contracts (to iCAD's installed base as well as OEM partners'), partnership deals with OEM's with new products, development projects and service contracts, and the recently penned MRI software development deal with Invivo. iCAD launched the first two products through this new Invivo relationship in March which should provide a more substantial revenue contribution in the second half of 2013.

    And as we've noted in the past, while CT colon CAD revenue has yet to gain much traction in the U.S. as a result of a dearth of reimbursement, management recently indicated they are seeing some growth

internationally and this remains a viable domestic growth opportunity with sufficient reimbursement. The additional data from the ACRIN study that were recently published could be a catalyst to eventually gaining Medicare reimbursement for CT colon CAD.

- **Cancer Therapy:** $3.9MM (+161% yoy) actual vs. $4.1MM estimate
  - Cancer therapy was up 161% yoy and up 19% sequentially. Growth is coming from both an increase in sales in the number of controllers and consumables. iCAD sold 11 controllers in Q2, up from 4 in Q2 2012 and from 9 sold in Q1 2013. The number of balloon applicators (consumables used for breast IORT) sold, which provides some insight into utilization (which will eventually be the long-term driver of Axxent related revenue and overall profit contribution) was 205 in Q2 2013, up from 161 in Q2 2012 and 175 in Q1 2013. While there will likely be some short-term variability in both controller and consumable sales, over the long-term consumable sales should show sustainable growth as the installed controller base expands. The services portion of the Therapy business, which includes service contracts and x-ray source revenue and should provide sustainable and recurring revenue for the long-term, is also exhibiting strong growth. Therapy services revenue continues to march up very nicely quarter-to-quarter and has exhibited sequential growth for at least the last nine straight quarters with the most recent quarter coming in at over $1 million. We expect services revenue to be a major contributor to iCAD's revenue over the long-term, which should also benefit gross margins.

    As we noted previously, growth appears to be coming from several fronts, including more favorable reimbursement, greater awareness of the benefits of IORT compared to traditional whole breast radiation therapy, and substantial interest and procedural volume (skin cancer treatment typically requires more than one visit) coming for use in non-melanoma skin cancer. Relative to reimbursement for IORT breast, an additional CPT code (for treatment planning for IORT) became effective in 2012 which has been an apparent catalyst to driving interest in breast IORT - however, we expect an even more substantial catalyst to come from CMS's recent decision to significantly increase reimbursement even more beginning in 2013 for treatment delivery.

    iCAD, who was instrumental in the pursuit of getting higher reimbursement for IORT treatment, notes that they expect to continue to be active in driving more demand for their Axxent system which will include awareness building efforts, post-marketing studies and continued lobbying for even greater reimbursement for breast IORT and initial reimbursement for skin. Management noted on the Q2 call that they continue to make progress with both regional and national payers on reimbursement with additional clinical data supporting use of brachytherapy in both breast and skin cancer. iCAD also initiated two new studies which are aimed at gaining reimbursement for skin cancer at the national level. The company also continues with its other awareness-building efforts including their recent attendance at the American Society of Breast Surgery meeting in Chicago - management noted on the Q2 call that they held a symposium at the conference which over 100 breast surgeons attended. iCAD expects to hold several more symposiums to help further drive awareness and utilization and help build the case for increased reimbursement. The company is also now tapping international markets with a handful of sites in Europe and one in Asia currently using Axxent. In April they announced distribution agreements for parts of China and Russia - launch in which is expected to happen following requisite regulatory approvals - potentially culminated in the next 12 months. More recently they penned a distribution agreement in Canada.

    We continue to see tremendous upside in the breast cancer indication. We think utilization remains relatively low and penetration of Axxent in the U.S. breast IORT market is likely only in the low single digits. Greater awareness and improved reimbursement could provide catalysts to ramp penetration, utilization and revenue. Relative to skin cancer, procedural volumes continue to be on the rise which has been a meaningful contributor to the success of iCAD's Therapy business. Management noted on the Q2 call that their Axxent system has treat about 1,400 skin cases in just the first two quarters of 2013, up from about 150 in the first half of 2012. The Therapy business should further benefit as additional indications come online, including for cervical cancer which is now still in the early launch phase.

EPS

Q2 EPS (excluding non-cash revaluation of warrant liability) of ($0.12) was slightly below our ($0.09) estimate as a result of the miss on the top-line which was partially offset by lower than modeled operating expenses ($5.7 million A vs $6.1 million E). EPS was significantly better than the ($0.25), excluding warrant liability revaluation, in Q2 2012. ICAD continues to keep a lid on operating expenses. Management reiterated their previous guidance on operating expenses which is to maintain them at the mid-to-low $6MM range (which, with anticipated revenue growth should result in nice operating leverage).

Cash
iCAD exited Q2 with $12.9 million in cash and equivalents, up slightly from $12.7 million at the end of Q1. Cash flow from operating activities was an inflow of $239k, up from an outflow of $1.2 million used in Q1. Adjusted EBITDA was approximately $434k in Q2 and $1.0 million in the first six months of 2013. This compares favorably to a EBITDA losses of $916k and $1.9 million in the comparable year earlier periods. Q2 2013 marks the fourth consecutive quarter of positive adjusted EBITDA. Given our expectations of significant revenue growth, gross margins maintained at 70%+, and incrementally increasing operating leverage, we continue to believe that the current cash balance along with cash from operations will be more than sufficient to fund the company for the foreseeable future.

VALUATION / RECOMMENDATION

We look for EPS of ($0.36) in 2013. We continue to model positive net income and EPS in 2014.

We continue to value iCAD based on competitor price/sales (P/S) and enterprise value /sales (EV/S) multiples. Using analyst's revenue estimates for the years 2013 and 2014, we calculated P/S and EV/S ratios from imaging (HOLX, MRGE) as well as surgical (VAR, ARAY, ISR) companies. The five companies currently trade at an average P/S-2013 of 1.8x and P/S-2014 of 1.3x and average EV/S-2013 of 2.0x and EV/S-2014 of 1.4x.

Based on the average of the 2013 and 2014 EV/S multiples iCAD is valued at $8.94/share. Based on the average of the 2013 and 2014 P/S multiples iCAD is valued at $6.65/share. We use the average of the two which values iCAD at approximately $7.80/share. We are maintaining our Outperform rating and recommend accumulating the stock up towards our $7.80/share price target.

FINANCIAL MODEL

iCAD Inc.

	2012 A	Q1A	Q2A	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Cancer Detection	$17,261.0	$4,638.0	$3,807.0	$3,702.5	$4,847.4	$16,995.0	$17,204.9	$17,631.7	$18,035.2
YOY Growth	*-24.2%*	*6.9%*	*-14.1%*	*-2.0%*	*2.9%*	*-1.5%*	*1.2%*	*2.5%*	*2.3%*
% of total revenue	*61.0%*	*58.5%*	*49.4%*	*43.3%*	*49.2%*	*49.9%*	*34.8%*	*23.6%*	*20.0%*
Therapy	$11,014.0	$3,292.0	$3,905.0	$4,844.7	$5,007.2	$17,049.0	$32,285.7	$57,214.0	$71,918.9
YOY Growth	*87.3%*	*64.3%*	*160.5%*	*10.0%*	*61.1%*	*54.8%*	*89.4%*	*77.2%*	*25.7%*
% of total revenue	*39.0%*	*41.5%*	*50.6%*	*56.7%*	*50.8%*	*50.1%*	*65.2%*	*76.4%*	*80.0%*
Total Revenues	$28,275.0	$7,930.0	$7,712.0	$8,547.3	$9,854.7	$34,043.9	$49,490.5	$74,845.7	$89,954.1
YOY Growth	*-1.3%*	*25.0%*	*30.0%*	*4.5%*	*26.1%*	*20.4%*	*45.4%*	*51.2%*	*20.2%*
Cost of Revenues	$8,244.0	$2,282.0	$2,490.0	$2,606.6	$2,824.4	$10,202.1	$14,329.9	$18,892.0	$19,096.9
Gross Income	$20,031.0	$5,648.0	$5,222.0	$5,940.6	$7,030.3	$23,841.9	$35,160.7	$55,953.7	$70,857.2
Gross Margin	*70.8%*	*71.2%*	*67.7%*	*69.5%*	*71.3%*	*70.0%*	*71.0%*	*74.8%*	*78.8%*
R&D	$7,769.0	$1,866.0	$1,756.0	$1,825.0	$1,765.0	$7,212.0	$8,955.0	$11,277.0	$12,214.0
% R&D	*27.5%*	*23.5%*	*22.8%*	*21.4%*	*17.9%*	*21.2%*	*18.1%*	*15.1%*	*13.6%*
Selling & Mktg	$10,708.0	$2,438.0	$2,337.0	$2,478.7	$2,749.5	$10,003.2	$14,500.7	$21,405.9	$25,007.3
% Sell&Mktg	*37.9%*	*30.7%*	*30.8%*	*29.0%*	*27.9%*	*29.4%*	*29.3%*	*28.6%*	*27.8%*
G&A	$6,941.0	$1,672.0	$1,602.0	$1,718.0	$2,008.0	$7,000.0	$8,660.8	$12,574.1	$14,572.6
% G&A	*24.5%*	*21.1%*	*20.8%*	*20.1%*	*20.4%*	*20.6%*	*17.5%*	*16.8%*	*16.2%*
Operating Income	($5,387.0)	($328.0)	($473.0)	($81.1)	$507.8	($373.3)	$3,044.1	$10,696.7	$19,063.4
Operating Margin	*-19.1%*	*-4.1%*	*-6.1%*	*-0.9%*	*5.2%*	*-1.1%*	*6.2%*	*14.3%*	*21.2%*
Other income	($531.0)	$437.0	($565.0)	$0.0	$0.0	($128.0)	$0.0	$0.0	$0.0
Interest income, net	($3,448.0)	($826.0)	($834.0)	($844.0)	($871.0)	($3,375.0)	($2,847.0)	($2,895.0)	($2,845.0)
Pre-Tax Income	($9,366.0)	($717.0)	($1,872.0)	($925.1)	($363.2)	($3,876.3)	$197.1	$7,801.7	$16,218.4
Taxes	$8.0	$0.0	$10.0	$0.0	$0.0	$0.0	$0.0	$1,053.2	$3,924.9
Tax Rate	*-0.1%*	*0.0%*	*-0.5%*	*0.0%*	*0.0%*		*0.0%*	*13.5%*	*24.2%*
Net Income	($9,374.0)	($717.0)	($1,882.0)	($925.1)	($363.2)	($3,876.3)	$197.1	$6,748.5	$12,293.5
YOY Growth	*74.3%*	*68.3%*	*36.1%*	*36.9%*	*86.6%*	*58.6%*	*105.1%*	*-3324.2%*	*-82.2%*
Net Margin	*-33.2%*	*-9.0%*	*-24.4%*	*-10.8%*	*-3.7%*	*-11.4%*	*0.4%*	*9.0%*	*13.7%*
EPS	($0.87)	($0.07)	($0.17)	($0.08)	($0.03)	($0.36)	$0.02	$0.50	$0.88
YOY Growth	*74.1%*	*68.5%*	*36.3%*	*37.5%*	*86.7%*	*59.0%*	*104.3%*	*-3183.6%*	*-74.4%*
Pro-forma adjustments	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pro-forma EPS	($0.87)	($0.07)	($0.17)	($0.08)	($0.03)	($0.36)	$0.02	$0.50	$0.88
Diluted Shares O/S	10,796	10,820	10,836	10,920	10,940	10,879	12,850	13,400	14,000

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APPENDIX

November 15, 2012. Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Revision to Quality Improvement Organization Regulations; Final Rule

e. Intraoperative Radiation Therapy (IORT) (APC 0412)

(1**) Background**

The AMA's CPT Editorial Panel created three new Category I CPT codes for intraoperative radiation therapy (IORT), effective January 1, 2012: CPT codes 77424 (Intraoperative radiation treatment delivery, x-ray, single treatment session); 77425 (Intraoperative radiation treatment delivery, electrons, single treatment session); and 77469 (Intraoperative radiation treatment management). As with all new CPT codes for CY 2012, these three codes were included in Addendum B to the CY 2012 OPPS/ASC final rule with comment period (available via the CMS Web site), effective on January 1, 2012. In accordance with our standard practice each year, our clinicians review the many CPT code changes that will be effective in the forthcoming year and make decisions regarding status indicators and/or APC assignments based on their understanding of the nature of the services. We are unable to include proposed status indicators and/or APC assignments in the proposed rule for codes that are not announced by the AMA's CPT Editorial Panel prior to the issuance of the proposed rule. Therefore, in accordance with our longstanding policy, we include, in the final rule with comment period, interim status indicators and/or APC assignments for all new CPT codes that are announced by the AMA's CPT Editorial Panel subsequent to the issuance of the OPPS/ASC proposed rule to enable payment for new services as soon as the codes are effective. We identified the new codes for IORT for CY 2012 in Addendum B to the CY 2012 OPPS/ASC final rule with comment period as being open to public comment by showing a comment indicator of ''NI'' and made interim status indicator assignments for each of these new IORT codes, based on our understanding of the clinical nature of the services they describe. Specifically, for CY 2012, we packaged these IORT service codes with the surgical procedures with which they are billed, assigning them Interim status indicators of ''N'' (Items and Services Packaged into APC Rates). We did so based on a policy that was adopted in the CY 2008 OPPS final rule with comment period (72 FR 66610 through 66659) to package services that are typically ancillary and supportive of a principal diagnostic or therapeutic procedure, which would generally include intraoperative services. Because IORT are intraoperative services furnished as a single dose during the time of the related surgical session, we packaged them into the payment for the principal surgical procedures with which they are performed based on claims data used for the CY 2012 OPPS/ASC final rule with comment period. Subsequent to issuance of the CY 2012 OPPS/ASC final rule with comment period, stakeholders provided comments on the interim status of these IORT service codes for CY 2012, asserting that these services are not ancillary to the surgical procedures, urging us to unpackage these codes, and requesting that we assign them to an APC reflective of the resources used to provide the IORT services. Commenters who responded to the CY 2012 OPPS/ASC final rule with comment period argued that IORT services described by CPT codes 77424 and 77425 are separate, distinct, and independent radiation treatment services from the surgical services to remove a malignant growth. According to the commenters, IORT is performed separately by a radiation oncologist and a medical physicist when there is concern for residual unresected cancer because of narrow margins related to the surgical resection. A number of the commenters provided varied estimates of the cost of IORT as between $4,000 and $7,000 per treatment, and some commenters cited a hospital survey of per treatment costs for the procedure described by CPT code 77424 of $4,441.17 and for the procedure described by CPT code 77425 of $6,897.50. One commenter stated that the x-ray intraoperative service described by CPT code 77424 has previously been reported with CPT code 0182T (High dose rate electronic brachytherapy, per fraction), which is a separately paid OPPS service. However, the commenter pointed out that it would not be proper to report intraoperative radiation therapy with CPT code 0182T because now CPT codes 77424 and 77425 more specifically and accurately describe the intraoperative radiation services. One commenter recommended that CPT code 77425 be mapped to a new technology APC.

(2) CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

Based on the public comments and information received on the IORT policies contained in the CY 2012 OPPS/ASC final rule with comment period, and after further review and consideration of those public comments and the clinical nature of the IORT procedures, we agreed that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. Therefore, for CY 2013, we proposed to unpackage CPT codes 77424 and 77425 and assign them to APC 0412, currently titled ''IMRT Treatment Delivery'' (77 FR 45124). We stated that IORT treatment services are clinically similar to other radiation treatment forms, such as IMRT treatment, which are assigned to APC 0412. Furthermore, we proposed to change the title of APC 0412 to ''Level III Radiation Therapy'' to encompass a greater number of clinically similar radiation treatment modalities. The CY 2013 proposed rule geometric mean cost for APC 0412, based on CY 2011 claims data, was approximately $496. We also proposed to monitor hospitals' costs for furnishing the services described by CPT codes 77424 and 77425. In the CY 2013 proposed rule, we stated that we believe that CPT code 77469 should receive equal treatment to other radiation management codes, such as CPT code 77431 (Radiation therapy management with complete course of therapy consisting of 1 or 2 fractions only) and CPT code 77432 (Stereotactic radiation treatment management of cranial lesion(s) (complete course of treatment consisting of 1 session)), which are assigned status indicator ''B'' (Codes that are not recognized by OPPS when submitted on an outpatient hospital Part B bill type (12x and 13x)) and are not paid under the OPPS. Therefore, we proposed that the appropriate status indicator code assignment for CPT code 77469 be ''B'' for nonpayable status under the OPPS for CY 2013, a change from its current CY 2012 status indicator assignment of ''N'' for packaged payment status. At its August 2012 meeting, the HOP Panel recommended that CMS assign CPT code 77424 and CPT code 77425 to APC 0313 Brachytherapy), and consider renaming the APC ''Brachytherapy and Intraoperative Radiation Therapy.'' The Panel also recommended that CMS present to the Panel cost data regarding CPT codes 77424 and 77425, when available or by the August 2013 Panel meeting. *Comment:* Many commenters supported the proposal to unpackage CPT codes 77424 and 77425, but objected to the proposed assignment of these codes to APC 0412. The commenters asserted that APC 0412 is neither reflective of the clinical characteristics nor the resources needed to perform the IORT services

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described by CPT codes 77424 and 77425. The commenters pointed out the clinical differences between IORT and IMRT, in that IORT provides a much higher dose of radiation During a single fraction (session) lasting about 45 minutes, while IMRT provides lower doses over multiple fractions lasting about 15 minutes. The commenters asserted that IMRT's cost over the full course of therapy is $17,000 to $20,000, much higher than IORT's cost. Many commenters requested that CMS assign CPT codes 77424 and 77425 to an appropriate APC based on clinical similarity to other radiation treatments and suggested that CMS use external cost data to estimate the costs of IORT, because cost data from hospital claims are not yet available for these new CPT codes. Some commenters recommended that CPT codes 77424 and 77425 be assigned to APC 0313 (Brachytherapy), which has a proposed payment rate of approximately $685, because the IORT services are more similar to brachytherapy services than the IMRT services currently assigned to APC 0412. These commenters asserted that both IORT and brachytherapy involve placement of a radiation source inside or next to the area of the body requiring treatment, while IMRT, which is a form of external beam radiation therapy, delivers radiation from outside the body. The commenters opined that CPT codes 77424 and 77425 and the APC 0313 brachytherapy procedures have similar resource costs, particularly because the X-ray based IORT procedure is comparable to high dose rate (HDR) brachytherapy, and the X-ray based IORT system may be used for the delivery of fractionated breast brachytherapy, often billed with CPT code 0182T (High dose rate electronic brachytherapy, per fraction), which is assigned to APC 0313. Several other commenters stated that IORT is very different than HDR brachytherapy, as well as IMRT and multi-fraction stereotactic radiosurgery, in terms of both clinical characteristics and resource costs. Commenters stated that IORT capital equipment can only be used for IORT in the operating room, and not for other forms of radiation therapy, resulting in less patient utilization over which to spread costs. These commenters recommended that CMS assign CPT codes 77424 and 77425 to APC 0067 (Level III Stereotactic Radiosurgery, MRgFUS, and MEG), which has a proposed payment rate of approximately $3,294. These commenters believed that IORT is more similar clinically to stereotactic radiosurgery (SRS) than IMRT, pointing out that SRS may be delivered in single or multiple fraction therapy and has many fewer (that is, 2 to 5) fractions, making it more similar to IORT, in that regard. A few commenters recommended that CMS assign IORT to a New Technology APC, with a wide range of recommended payment rates, from approximately $4,000 to approximately $7,000, citing various data estimates and sources including a survey of hospitals. Regarding our proposal to change the status indicator for CPT code 77469 to ''B'' and make the service non-payable, one commenter supported the proposed change on the basis that it is consistent with our policy regarding other radiation treatment management codes. *Response:* We appreciate all of the feedback we received on the CY 2012 interim status indicator assignment of ''N'' to CPT codes 77424 and 77425 and the CY 2013 proposal to assign these CPT codes to APC 0412. As stated in the CY 2013 OPPS/ASC proposed rule and described above, we agree with the commenters that IORT services are not the typical intraoperative services that we package, as they are not integral to or dependent upon the surgical procedure to remove a malignancy that precedes IORT. We agree with commenters that the resource costs of APC 0412 do not fit well with single fraction radiation therapy technologies, such as IORT. However, we believe the resource costs of IORT can be accommodated by one of the existing APCs for radiation therapy, and therefore, a new technology APC assignment is not needed. From a clinical standpoint, we agree with commenters that the procedures described by CPT codes 77424 and 77425 share important characteristics with SRS, particularly because SRS may be a single fraction therapy or involve many fewer fractions than IMRT. Based on the range of claimed costs provided by the commenters, which are all based on external costs, as we do not yet have claims data, there is clearly a wide range of reported or estimated costs for IORT services, and, as some commenters indicate, there may be a difference in the cost structures of CPT codes 77424 and 77425. After consideration of the public comments we received, we believe that an appropriate initial APC assignment for CPT codes 77424 and 77425 is APC 0065 (Level I Stereotactic Radiosurgery, MRgFUS, and MEG), in terms of clinical characteristics, and the range of estimated costs for IORT services. Therefore, for CY 2013, we are assigning CPT codes 77424 and 77425 to APC 0065, which has a CY 2013 final geometric mean cost of approximately $1,006. We will review the APC assignment of CPT codes 77424 and 77425, individually, once we have OPPS hospital claims data. Regarding the Panel recommendation that we present to the Panel cost data regarding CPT codes 77424 and 77425, we agree to provide cost data from claims for these service codes when available.

HISTORICAL ZACKS RECOMMENDATIONS



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