October 30, 2013

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Icad Inc (ICAD-NASDAQ)

ICAD: Strong Detection Revenue, Skin Utilization

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	10/29/2013
Current Price (10/29/13)	$8.50
Target Price	**$9.25**

OUTLOOK

Revenue is up 17% and operating expenses down 6% through first 9 months of 2013. Therapy growth coming from strong demand in non-melanoma skin cancer and improved reimbursement for IORT breast. 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 looks like it is marking an important inflection point for iCAD.

We remain highly positive on ICAD and management's ability to continue to grow the top and bottom lines. Our rec has moved to Neutral based on valuation and a recent nice run up in the stock price. Our price target is $9.25/share.

SUMMARY DATA

52-Week High	**$10.18**
52-Week Low	**$1.85**
One-Year Return (%)	**342.71**
Beta	**1.27**
Average Daily Volume (sh)	**97,227**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$92**
Short Interest Ratio (days)	**4.84**
Institutional Ownership (%)	**18**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.2**
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	**N/A**
Zacks Rank	**N/A**

Risk Level	**Average,**
Type of Stock	**Small-Growth**
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	8,290 A	8,843 E	32,775 E
2014					47,551 E
2015					71,932 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	-$0.05 A	-$0.06 E	-$0.35 E
2014					$0.00 E
2015					$0.46 E

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

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WHAT'S NEW…

Q3 2013 RESULTS

iCAD (ICAD) announced financial results for the third quarter ending September 30th. Revenue came in only slightly softer than our number and while only eking out just better than 1% yoy growth (note that Q3 2012 was a fairly strong quarter and a tough comp), the details behind the itemized revenue lines continue to paint the picture that the recent shift towards a greater focus on recurring and services oriented revenue streams, primarily in the Detection segment, are paying off. Detection revenue posted 14% growth in Q3 with management noting that they continue to grow the number of customers covered by service agreements, on both a yoy as well as qoq basis. And while revenue in the Therapy business fell almost 10% in Q3, utilization, particularly in skin procedures, continues to trend upwards with the number of skin lesions treated quadrupling from Q3 2012. Therapy revenue can fluctuate somewhat widely from q-to-q given the variability in controller placements - important is that we continue to be encouraged by what we're seeing in terms of utilization - which is the long-term driver of revenue and margins in this segment. Through the first nine months of 2013, Therapy revenue is up 41%.

Much of the recent growth in Therapy is coming from skin which we think will continue given catalysts such as positive clinical trial data supporting the use of eBx in non-melanoma skin cancer, fairly rapid geographic growth in reimbursement and overall increased awareness (by both dermatologists as well as consumers) of its benefits over traditional surgical excision. ICAD remains very active in promoting at all these levels. We think it is reasonable to expect that an increase in reimbursement, from both an uptake on the payer side as well as level of reimbursement, will be facilitated with additional positive clinical data. This will be supported by published manuscripts and presentations such as the recent presentation at ASTRO detailing positive three-year follow up data on non-melanoma skin cancer patients (n=187) treated with Xoft.

Recent and upcoming product launches and an increase in service and recurring revenue streams remain the catalysts to growing the Detection segment. Management has indicated that the recently introduced PowerLook platform is seeing significant interest. Demand is coming from both OEM partners as well as upgrades to ICAD's installed base. Management also pointed towards increased service contract sales to GE's installed base as benefitting the recent Detection revenue growth. Tomosynthesis remains one of the major expected growth catalysts over the mid to long term.

Growth in procedural volumes and the shift towards greater services based revenue also looks to be benefitting margins with the gross margin holding up impressively despite the bite from the recently implemented medical device tax. Management continues to be diligent on watching operating expenses which has had a dramatically positive impact on improving the bottom line results and on the cash flow statement. Operating expenses have fallen almost 6% through the first nine months of 2013 compared to the same period in 2012 while revenue has grown almost 17% over the same period. Importantly, the cuts in operating expenses have not compromised clinical research or marketing and promotional activities, which include attendance at industry events and conferences and activities related to promoting reimbursement of IORT. We continue to expect to see additional operating leverage with further revenue growth, the combination of which, along with an even wider gross margin, we think will result in positive earnings for the full year 2014. Management also noted on the Q3 call that they expect to generate positive cash flow in Q4.

Revenue
Revenue of $8.3MM was up 1% y-o-y and about 3% lower than our $8.6MM estimate - the difference due to 18% lower than modeled Therapy revenue which was partially offset by a 16% beat in Detection revenue.

- **Cancer Detection:** $4.3MM actual (+14% yoy) vs. $3.7MM estimate
  - Total product revenue in cancer detection was about $2.3 million, up from about $2.0 million in Q3 2012 and better than our $2.0 million estimate. It's been well detailed that Detection-related revenue growth had been hampered in the past given ICAD's previous focus on squeezing the last vestiges of the benefits from the conversion by imaging facilities from film-based to digital mammography. While ICAD does not break out the specific film-to-digital conversion related revenue, we think it's now relatively minimal. We point this out as it provides even greater insight into the success that ICAD has had in growing of revenue from the Detection segment's new product lines as well as their services and subscription-based offerings. Q3 saw Detection product revenue growth of 11% despite a likely precipitous drop in film-to-digital conversion related revenue.

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. We think it's now obvious that this is bearing fruit with Detection services revenue growing 22% in Q4 2012 and almost 19% through the first nine months of 2013. Management noted that the number of customers under service agreements has increased by 14% since the end of 2012. 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 expect the Detection segment to remain on track for 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:** $4.0MM (-10% yoy) actual vs. $4.8MM estimate
  - Cancer therapy fell 10% yoy but was up 2% sequentially. Controller sales can be somewhat variable q-to-q and fell from 12 sold in Q3 2012 to 10 sold in Q3 2013 so despite nice growth in utilization and consumables sales, the drop in controllers sales resulted in a decrease in total Therapy revenue. Importantly utilization is increasing. ICAD sold 194 balloon applicators with over 1,000 skin lesions treated in the most recent quarter compared to 150 applicators (+29%) and 250 lesions treated in the year earlier period. As the installed controller base grows, growth in consumables revenue should accelerate.

    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.

    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 again noted on the earnings call that they continue to make progress with both regional and national payers on reimbursement - most recently noting that as of Nov 1st 19 states will have a "positive policy" related to non-melanoma skin cancer whereas this stood at just 10 states in July of this year. Clearly the reimbursement picture is improving which has almost certainly aided uptake and utilization of Xoft for skin cancer.

    Much of the recent growth in Therapy is coming from skin which we think will continue given catalysts such as positive clinical trial data supporting the use of eBx in non-melanoma skin cancer, fairly rapid geographic growth in reimbursement and overall increased awareness (by both dermatologists as well as consumers) of its benefits over traditional surgical excision. ICAD remains very active in promoting at all these levels. We think it is reasonable to expect that an increase in reimbursement, from both an uptake on the payer side as well as level of reimbursement, will be facilitated with additional positive clinical data. This will be supported by published manuscripts and presentations such as the recent presentation at ASTRO detailing positive three-year follow up data on non-melanoma skin cancer patients (n=187) treated with Xoft.

    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. 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

Q3 EPS (excluding non-cash revaluation of warrant liability) of approximately ($0.11) was slightly below our ($0.08) estimate as a result of the miss on the top-line and slightly higher operating expenses (although very much in-line with mgmt's guidance), which was partially offset by a wider gross margin (71.5% A vs. 69.5% E). EPS was better than the ($0.12), excluding warrant liability revaluation, in Q3 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 Q3 with $10.2 million in cash and equivalents, down from $12.9 million at the end of Q2. Cash used in operating activities was an outflow of $2.5 million, which included a $2.3 million increase in A/R. Management addressed the A/R on the call, noting that they adjusted terms based on the type of customer but indicated the credit is quality and expected the balance to come down. Adjusted EBITDA was approximately $545k in Q3 and $1.6 million in the first nine months of 2013. This compares favorably to EBITDA of $240k and ($1.6) million in the comparable year earlier periods. Q3 2013 marks the fifth 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 ($0.35) 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 2.8x and P/S-2014 of 1.9x and average EV/S-2013 of 3.0x and EV/S-2014 of 2.1x.

Based on the average of the 2013 and 2014 EV/S multiples iCAD is valued at $10.55/share. Based on the average of the 2013 and 2014 P/S multiples iCAD is valued at $8.00/share. We use the average of the two which values iCAD at approximately $9.25/share. The stock has had a nice run since our last update and is now trading just slightly below where we see fair value. As such we are moving our recommendation to Neutral.

FINANCIAL MODEL

iCAD Inc.

	2012 A	Q1A	Q2A	Q3A	Q4E	2013 E	2014 E	2015 E	2016 E
Cancer Detection	$17,261.0	$4,638.0	$3,807.0	$4,310.0	$4,672.2	$17,427.2	$18,444.0	$19,825.9	$21,038.5
YOY Growth	*-24.2%*	*6.9%*	*-14.1%*	*14.0%*	*-0.8%*	*1.0%*	*5.8%*	*7.5%*	*6.1%*
% of total revenue	*61.0%*	*58.5%*	*49.4%*	*52.0%*	*52.8%*	*53.2%*	*38.8%*	*27.6%*	*24.8%*
Therapy	$11,014.0	$3,292.0	$3,905.0	$3,980.0	$4,170.3	$15,347.3	$29,106.6	$52,106.5	$63,918.3
YOY Growth	*87.3%*	*64.3%*	*160.5%*	*-9.6%*	*34.2%*	*39.3%*	*89.7%*	*79.0%*	*22.7%*
% of total revenue	*39.0%*	*41.5%*	*50.6%*	*48.0%*	*47.2%*	*46.8%*	*61.2%*	*72.4%*	*75.2%*
Total Revenues	$28,275.0	$7,930.0	$7,712.0	$8,290.0	$8,842.6	$32,774.6	$47,550.5	$71,932.4	$84,956.8
YOY Growth	*-1.3%*	*25.0%*	*30.0%*	*1.3%*	*13.1%*	*15.9%*	*45.1%*	*51.3%*	*18.1%*
Cost of Revenues	$8,244.0	$2,282.0	$2,490.0	$2,364.0	$2,497.2	$9,632.2	$13,487.3	$17,944.4	$17,860.4
Gross Income	$20,031.0	$5,648.0	$5,222.0	$5,926.0	$6,345.4	$23,142.4	$34,063.3	$53,987.9	$67,096.4
Gross Margin	*70.8%*	*71.2%*	*67.7%*	*71.5%*	*71.8%*	*70.6%*	*71.6%*	*75.1%*	*79.0%*
R&D	$7,769.0	$1,866.0	$1,756.0	$2,112.0	$1,765.0	$7,499.0	$8,955.0	$11,277.0	$12,214.0
% R&D	*27.5%*	*23.5%*	*22.8%*	*25.5%*	*20.0%*	*22.9%*	*18.8%*	*15.7%*	*14.4%*
Selling & Mktg	$10,708.0	$2,438.0	$2,337.0	$2,617.0	$2,697.0	$10,089.0	$13,932.3	$20,572.7	$23,618.0
% Sell&Mktg	*37.9%*	*30.7%*	*30.8%*	*30.8%*	*30.5%*	*30.8%*	*29.3%*	*28.6%*	*27.8%*
G&A	$6,941.0	$1,672.0	$1,602.0	$1,551.0	$1,745.0	$6,570.0	$8,321.3	$12,084.6	$13,763.0
% G&A	*24.5%*	*21.1%*	*20.8%*	*18.7%*	*19.7%*	*20.0%*	*17.5%*	*16.8%*	*16.2%*
Operating Income	($5,387.0)	($328.0)	($473.0)	($354.0)	$138.4	($1,015.6)	$2,854.6	$10,053.6	$17,501.4
Operating Margin	*-19.1%*	*-4.1%*	*-6.1%*	*-4.3%*	*1.6%*	*-3.1%*	*6.0%*	*14.0%*	*20.6%*
Other income	($531.0)	$437.0	($565.0)	$628.0	$0.0	$500.0	$0.0	$0.0	$0.0
Interest income, net	($3,448.0)	($826.0)	($834.0)	($807.0)	($810.0)	($3,277.0)	($2,847.0)	($2,895.0)	($2,845.0)
Pre-Tax Income	($9,366.0)	($717.0)	($1,872.0)	($533.0)	($671.6)	($3,792.6)	$7.6	$7,158.6	$14,656.4
Taxes	$8.0	$0.0	$10.0	$56.0	$0.0	$0.0	$0.0	$966.4	$3,546.8
Tax Rate	*-0.1%*	*0.0%*	*-0.5%*	*-10.5%*	*0.0%*		*0.0%*	*13.5%*	*24.2%*
Net Income	($9,374.0)	($717.0)	($1,882.0)	($589.0)	($671.6)	($3,792.6)	$7.6	$6,192.2	$11,109.5
YOY Growth	*74.3%*	*68.3%*	*36.1%*	*59.8%*	*75.1%*	*59.5%*	*100.2%*	*-81037.4%*	*-79.4%*
Net Margin	*-33.2%*	*-9.0%*	*-24.4%*	*-7.1%*	*-7.6%*	*-11.6%*	*0.0%*	*8.6%*	*13.1%*
EPS	($0.87)	($0.07)	($0.17)	($0.05)	($0.06)	($0.35)	$0.00	$0.46	$0.79
YOY Growth	*74.1%*	*68.5%*	*36.3%*	*60.0%*	*75.4%*	*59.8%*	*100.2%*	*-77707.2%*	*-71.7%*
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)	($0.05)	($0.06)	($0.35)	$0.00	$0.46	$0.79
Diluted Shares O/S	10,796	10,820	10,836	10,849	10,940	10,861	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.

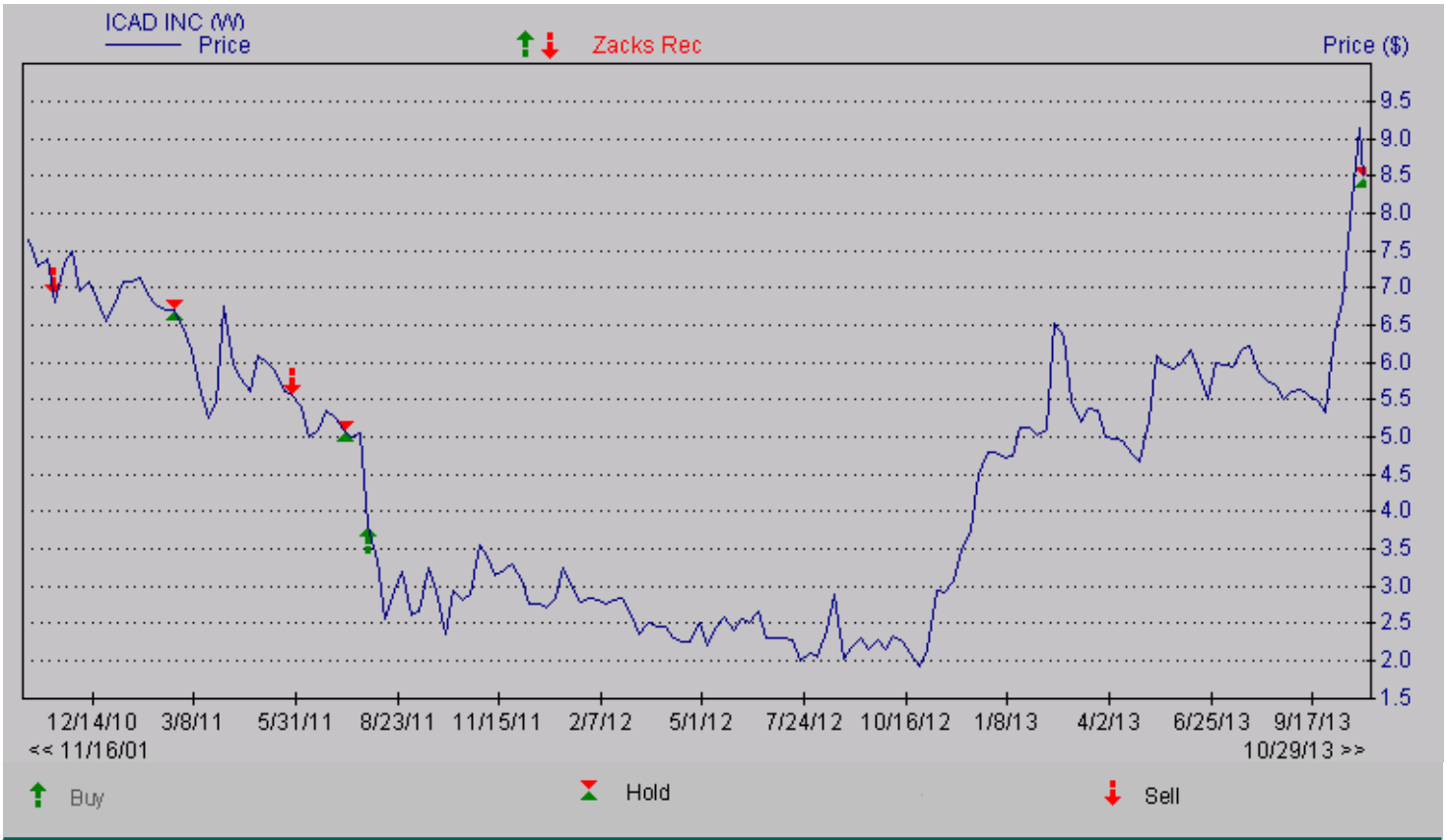
(2) CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

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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