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Icad Inc (ICAD-NASDAQ)

ICAD: Q1 Results - Detection Segment Returns To Growth, Therapy Up 64%!

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	07/29/2011
Current Price (05/01/13)	$4.99
Target Price	**$8.25**

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 and $8.25/share price target.

SUMMARY DATA

52-Week High	**$6.90**
52-Week Low	**$1.75**
One-Year Return (%)	**111.44**
Beta	**1.42**
Average Daily Volume (sh)	**46,965**
Shares Outstanding (mil)	**11**
Market Capitalization ($mil)	**$54**
Short Interest Ratio (days)	**2.82**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**16**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-4.8**
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	**100**
Zacks Rank	**N/A**

Risk Level	**N/A,**
Type of Stock	**Small-Value**
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	8,571 E	9,866 E	10,725 E	37,091 E
2014					50,921 E
2015					80,557 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	-$0.09 E	-$0.05 E	-$0.02 E	-$0.23 E
2014					$0.05 E
2015					$0.54 E

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

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WHAT'S NEW…

Q1 2013 RESULTS

iCAD (ICAD) announced financial results for the first quarter ending March 31, 2013 on April 30th. Results were very strong with revenue at the highest level since Q3 2011 and over 10% better than our estimate. The beat wasn't just confined to the top-line as management's continued efforts in limiting operating expense growth and maintaining their very healthy gross margins despite a bite from the newly enacted medical device tax resulted in operating income about $414k better than our estimate. At the risk of being accused of beating a dead horse, we think it's again worth reiterating the commendable job management has done with accelerating growth of the Therapy business, decelerating the slide in Detection revenue (which actually showed positive growth in the most recent quarter), and maintaining the beefy gross margins all at the same time that they've slashed operating expenses. 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 update 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).

On the operational front, Axxent console and consumables/service-related sales continue to closely track our estimates with the number of console sales (9) in the quarter actually coming in slightly better than our estimate (8) and consumables/service-related sales of about $900k, right in-line with our $965k estimate. Utilization in both breast IORT and non-melanoma skin cancer continues to accelerate and management remains encouraged by the recent trends and market fundamentals such as greater reimbursement (CMS's Final Rule more than doubled reimbursement for breast IORT) and growing interest in and awareness for use in skin cancer to help catalyze even more robust growth in 2013 and beyond. Use in skin cancer has been a particularly positive boon and, perhaps, somewhat greater than initially anticipated. Similar to breast, skin use to-date has largely been driven by positive patient outcomes (which is not always the facilitator of increased utilization of medical devices) - an improvement in reimbursement would likely further accelerate adoption and utilization. With the Axxent system barely penetrating just 1% of the U.S. breast IORT market so far, there's potential huge upside for iCAD, particularly when also considering the other applications, namely skin and cervical cancers. Cervical cancer is only second behind breast as the most common cancer among women and pursuit of this area seems a natural addition to ICAD's women's health focus. FDA clearance of a cervical applicator was received in Q1 and is expected to launch in Q2.

Growth in the Detection business, which until recently had been hampered by the ever dwindling number of mammography facilities that had yet to switch from film to digital, now finally looks to turn the corner. Management has done an impressive job of righting this business over the last couple of years when it became evident that the legacy products business may not produce organic growth. New product launches (including PowerLook AMP) and iCAD's recent shift in strategy towards a greater reliance on recurring revenue, services and a conventional software business model has really begun to pay dividends. New product introductions should follow and ICAD is looking to capitalize on the next generation of image enhancements with the switch from 2D to 3D images and is working on tomosynthesis (3D) products. The next catalyst in the Detection business could come from an agreement with Invivo (part of Philips Healthcare) that ICAD first alluded to on the Q4 call in which ICAD will develop MRI analysis software which will be incorporated into Invivo's MRI products (new products as well as products already in the field). With a very substantial installed base, and much larger than ICAD's, this provides the company with a greatly expanded footprint and captive customer base in which to sell upgrades and new products to. This partnership also easily facilitates an international presence for ICAD. The initial focus will be MRI products for prostate and breast but the duo is working on other products and applications as well. The first products related to this agreement are expected to begin rolling out in Q2.

Revenue
Revenue of $7.9MM was up 25% y-o-y and about 10% better than our $7.2MM estimate.

- **Cancer Detection:** $4.6MM actual (+7% yoy) vs. $4.3MM estimate
    - Total product revenue in cancer detection was about $2.7MM, up from about $2.6MM in Q1 2012 and better than our $2.4MM estimate. On the earnings call management noted strong sales to their OEM

partners such as GE and Siemens as a contributor to the sales growth. There was also a small ($50k) revenue contribution from work related to the Invivo service agreement.

Going forward we think there's a number of near-term catalysts which can facilitate growth of the Detection segment. These include new products such as PowerLook Amp, iCAD's next-generation mammography CAD system which includes highly sought after breast density functionality, CAD for tomosynthesis (3D mammography) which is currently in the planning phase with an initial introduction potentially in 2014, more annual licensing agreements which may appeal to a broader customer base, 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 just-announced MRI software development deal with Invivo. 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 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:** $3.3MM (+64% yoy) actual vs. $2.9MM estimate

  - Cancer therapy revenue was up 64% yoy and up 6% sequentially - the sequential increase due to a greater number of Axxent controllers sold in the current quarter, with related consumables/service revenue about flat over the same periods. As we've noted in the past, both controller and consumables sales may be somewhat variable quarter-to-quarter. iCAD sold 9 controllers in the quarter, compared to 6 in Q1 2012 and 8 in Q4 2012. 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 175 in Q1 2013, down from 233 in Q4 2012 but up considerably from 125 sold in Q1 2012. The reason for the sequential decrease is due at least in part to some delay between when a customer purchases a console and when it's put into use (at which point they purchase applicators) as well as bulk applicator purchases which can create some lumpiness quarter-to-quarter. Importantly, applicator sales are clearly trending upward. And despite the sequential decrease in applicator sales, in aggregate revenue from the other components of Therapy-related consumables and services (x-ray sources, service contracts, etc) increased on both a sequential and yoy basis - with management noting that the number of minutes purchased under these source agreements having been increasing with increased procedure volume - which directly points to greater utilization. Relative to skin cancer, procedure volumes increased about 50% sequentially and management indicated this rate could accelerate even significantly more going forward based on what they're seeing in terms of demand.

    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 (CMS's Final Rule, discussed below) 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. 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.

    Relative to skin cancer, procedure volumes have similarly been significantly increasing with an estimated 827 procedures performed in 2012, up from 200 in 2011. Q2 volumes were 625, up from 417 in Q4 2012. iCAD will also be aggressive in pushing demand and interest in Axxent for skin cancer. This includes presentations and other awareness-building efforts. In April a poster presentation of Xoft in skin cancer treatment of 172 patients was made at the American Brachytherapy Society Meeting - data from this study was also published in the journal *Brachytherapy*.

iCAD also expects to have their cervical applicator, which just received FDA clearance, launched during Q2.

As we noted in our last update, utilization remains fairly low. By our estimates each installed console is only being used approximately 3x per month for IORT breast cancer therapy. This procedural volume rate per unit will almost certainly substantially increase as demand for IORT continues to grow and providers look to maximize utilization (in breast as well as skin and other cancers) and speed break even on the cost of the (~$275k) of the console. As the utilization rate grows so will iCAD's revenue growth rate. We model a very incremental step-up in utilization over the next several years which could actually end up being somewhat conservative. A larger installed base means greater recurring revenue from consumables including balloon catheters and x-ray sources as well as annual service contract revenue, all of which we estimate generate relatively high margins to iCAD compared to that of the consoles.

EPS

Q1 EPS (excluding non-cash revaluation of warrant liability) of ~($0.11) beat our ($0.14) estimate as a result of the beat on the top line, slightly offset by a marginally narrower (71.2% A vs. 71.8% E) gross margin. EPS was much improved from the ~($0.27), excluding warrant liability revaluation, in Q1 2012. We also note that the GM remains very strong despite about a 160 basis point bite from the newly enacted medical device tax. ICAD continues to keep a lid on operating expenses, which were just about dead-on with our estimate ($5.98MM A vs. $5.92MM E) even with the beat on revenue. 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 Q1 with $12.7MM in cash and equivalents, down from $13.9MM in Q4 2012. Cash flow from operating activities was an outflow of about $1.2MM, down from about $3.7MM used in Q1 2012. Adjusted EBITDA was approximately $592k in the most recent quarter, significantly improved from ($967)k in Q1 2012. Management noted on the call that they expect to be approximately cash flow break-even in Q2. Given our expectations of significant revenue growth, gross margins maintained at 70%+, and incrementally increasing operating leverage, we believe that the current cash balance along with cash from operations will be more than sufficient to fund the company for the foreseeable future.

CMS FINAL RULE MORE THAN DOUBLES PROPOSED IORT REIMBURSEMENT

In the Final Rule for the Hospital Outpatient Prospective Payment System for 2013 (see our Appendix for the full detail), reimbursement for IORT was increased from the previous proposed $496 to $1,006. We expect the recent beneficial changes to reimbursement for IORT to have a positive influence on uptake and interest in the procedure as well as on sales of iCAD's Axxent system and consumables.

As a reminder relative to IORT reimbursement, amounts for 2012 unexpectedly bundled the IORT therapy with the surgery - this limited the economics for radiation oncologists to use Axxent. After considerable objection from the IORT-participant community, including iCAD, that reimbursement for IORT therapy should be broken out separately given that it is not integral to surgery to remove cancerous tissue, CMS agreed and proposed separate reimbursement of $496 (under APC code 0412, "IMRT Treatment Delivery", the title of which was proposed to change to "Level III Radiation Therapy"). Then after a further public comment period, in November 2012, CMS announced its Final Rule (see our appendix which includes CMS's full discussion on IORT in their Final Rule) which determined that the IORT procedural codes in question (77424 and 77425) should be mapped to a different APC code (0065, "Level I Stereotactic Radiosurgery, MRgFUS, and MEG) - which had the effect of increasing IORT reimbursement to $1,006.

VALUATION / RECOMMENDATION

As there were no material surprises in Q1 or on the conference call, we have made only minor changes to our model following Q1 results. We look for EPS of ($0.23) in 2013, changed from ($0.29) - almost all of the difference related to the beat in Q1. 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 2.1x and P/S-2014 of 1.6x and average EV/S-2013 of 2.0x and EV/S-2014 of 1.5x.

Based on the average of the 2013 and 2014 EV/S multiples iCAD is valued at $8.90/share. Based on the average of the 2013 and 2014 P/S multiples iCAD is valued at $7.35/share. We use the average of the two which values iCAD at approximately $8.25/share. We are maintaining our Outperform rating and recommend accumulating the stock up towards our $8.25/share price target.

FINANCIAL MODEL

iCAD Inc.

	2012 A	Q1A	Q2E	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Cancer Detection	$17,261.0	$4,638.0	$4,513.1	$3,832.8	$4,501.1	$17,484.9	$18,270.3	$19,434.8	$20,520.7
YOY Growth	*-24.2%*	*6.9%*	*1.8%*	*1.4%*	*-4.4%*	*1.3%*	*4.5%*	*6.4%*	*5.6%*
% of total revenue	*61.0%*	*58.5%*	*52.7%*	*38.8%*	*42.0%*	*47.1%*	*35.9%*	*24.1%*	*21.5%*
Therapy	$11,014.0	$3,292.0	$4,057.4	$6,033.2	$6,223.7	$19,606.3	$32,650.6	$61,122.0	$74,912.0
YOY Growth	*87.3%*	*64.3%*	*170.7%*	*37.0%*	*100.2%*	*78.0%*	*66.5%*	*87.2%*	*22.6%*
% of total revenue	*39.0%*	*41.5%*	*47.3%*	*61.2%*	*58.0%*	*52.9%*	*64.1%*	*75.9%*	*78.5%*
Total Revenues	$28,275.0	$7,930.0	$8,570.5	$9,866.0	$10,724.7	$37,091.2	$50,920.9	$80,556.8	$95,432.7
YOY Growth	*-1.3%*	*25.0%*	*44.5%*	*20.6%*	*37.2%*	*31.2%*	*37.3%*	*58.2%*	*18.5%*
Cost of Revenues	$8,244.0	$2,282.0	$2,566.2	$3,160.3	$3,324.1	$11,332.6	$14,584.5	$21,392.4	$20,285.1
Gross Income	$20,031.0	$5,648.0	$6,004.4	$6,705.7	$7,400.6	$25,758.7	$36,336.4	$59,164.4	$75,147.6
Gross Margin	*70.8%*	*71.2%*	*70.1%*	*68.0%*	*69.0%*	*69.4%*	*71.4%*	*73.4%*	*78.7%*
R&D	$7,769.0	$1,866.0	$1,825.0	$1,825.0	$1,765.0	$7,281.0	$8,955.0	$11,277.0	$12,214.0
% R&D	*27.5%*	*23.5%*	*21.3%*	*18.5%*	*16.5%*	*19.6%*	*17.6%*	*14.0%*	*12.8%*
Selling & Mktg	$10,708.0	$2,438.0	$2,639.7	$2,841.4	$2,992.2	$10,911.3	$14,919.8	$23,039.2	$26,530.3
% Sell&Mktg	*37.9%*	*30.7%*	*30.8%*	*28.8%*	*27.9%*	*29.4%*	*29.3%*	*28.6%*	*27.8%*
G&A	$6,941.0	$1,672.0	$1,660.0	$1,755.0	$2,008.0	$7,095.0	$8,911.2	$13,533.5	$15,460.1
% G&A	*24.5%*	*21.1%*	*19.4%*	*17.8%*	*18.7%*	*19.1%*	*17.5%*	*16.8%*	*16.2%*
Contingent Consideration	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Goodwill Impairment	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	($5,387.0)	($328.0)	($120.4)	$284.3	$635.4	$471.4	$3,550.4	$11,314.6	$20,943.2
Operating Margin	*-19.1%*	*-4.1%*	*-1.4%*	*2.9%*	*5.9%*	*1.3%*	*7.0%*	*14.0%*	*21.9%*
Other income	($531.0)	$437.0	$0.0	$0.0	$0.0	$437.0	$0.0	$0.0	$0.0
Interest income, net	($3,448.0)	($826.0)	($830.0)	($844.0)	($871.0)	($3,371.0)	($2,847.0)	($2,895.0)	($2,845.0)
Pre-Tax Income	($9,366.0)	($717.0)	($950.4)	($559.7)	($235.6)	($2,462.6)	$703.4	$8,419.6	$18,098.2
Taxes	$8.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$1,136.6	$4,379.8
Tax Rate	*-0.1%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*		*0.0%*	*13.5%*	*24.2%*
Net Income	($9,374.0)	($717.0)	($950.4)	($559.7)	($235.6)	($2,462.6)	$703.4	$7,282.9	$13,718.4
YOY Growth	*74.3%*	*68.3%*	*67.7%*	*61.8%*	*91.3%*	*73.7%*	*128.6%*	*-935.4%*	*-88.4%*
Net Margin	*-33.2%*	*-9.0%*	*-11.1%*	*-5.7%*	*-2.2%*	*-6.6%*	*1.4%*	*9.0%*	*14.4%*
EPS	($0.87)	($0.07)	($0.09)	($0.05)	($0.02)	($0.23)	$0.05	$0.54	$0.98
YOY Growth	*74.1%*	*68.5%*	*68.0%*	*62.2%*	*91.4%*	*74.0%*	*124.2%*	*-892.9%*	*-80.3%*
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)	($0.09)	($0.05)	($0.02)	($0.23)	$0.05	$0.54	$0.98
Diluted Shares O/S	10,796	10,820	10,880	10,920	10,940	10,890	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.

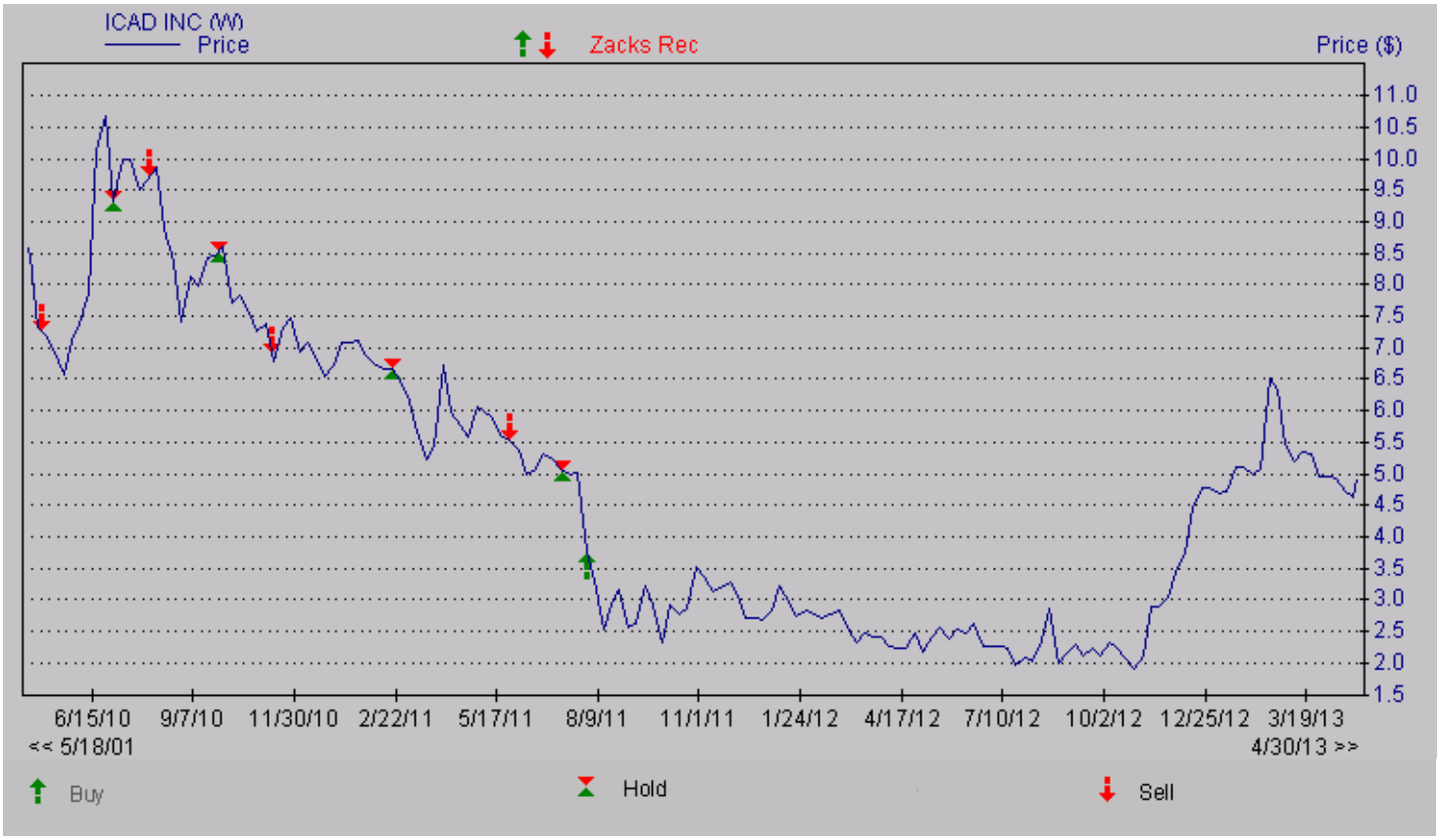
(2) CY 2013 Proposals for CPT Codes 77424, 77425, and 77469

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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