To: Michael Leavitt, Kerry Weems

As a volunteer with the Leukemia and Lymphoma Society I am writing to to exp concern over the recent CMS determination about the payment levels for radioimmunotherapies that are set in the calendar year 2008 hospital outpatier prospective payment system (HOPPS). Specifically, I would like you to impleme three recommendations in a letter to you from George Dahlman, Senior Vice Pr Public Policy at the Leukemia and Lymphoma Society.

These recommendations are: "(1) The Centers for Medicare & Medicaid Service: should consider the radioimmunotherapy regimen a specified covered outpatier SCOD. In CY 2008 rule, the agency improperly splits the radioimmunotherapy r into separate elements and considers the initial doses to be diagnostic rather th therapeutic doses. This is at odds with the Food and Drug Administration labelir products and with current practice. (2) CMS should cover the cost of compound radioimmunotherapies. Elimination of the compounding fee creates another obs the willingness of institutions to make this therapy available to their patients, b these institutions find the payment inadequate to meet their costs. (3) The age consider setting payment for radioimmunotherapies on the basis of 106 percen average sales price (ASP) or a composite ambulatory payment classification (A would reflect the entire cost of the radioimmunotherapy regimen. We understar APC Advisory Panel reviewed these options at a recent meeting, and we urge C consider these proposals. Because the effective date of the payment system is an ASP-based system may represent the most feasible alternative."

Mr. Secretary, this issue is of critical importance to those in the lymphoma com who live with this disease and recognize that this form of treatment may truly b saving one. I urge you to please support this request to reconsider the paymen the radioimmunotherapies.

cc: Kerry Weems, Administrator
Centers for Medicare & Medicaid Services

Sincerely

Helene King

Helene King

Back

(202) 628-5100

one day Surgery LLC

December 21, 2007

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMSs new proposals and classifications will hinder access.

The first issue relates to the update to the conversion factor while ASCs are facing losses, hospital outpatient departments will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

Secondly, I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT code 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72295 (discography interpretation and supervision in lumbar spine) or CPT Code 72285 (discography interpretation and supervision is cervical spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in as ASC setting.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary for ASCs and HOPDs otherwise the disparity in reimbursements become larger over time.

To avoid exponential increases in procedures performed in all settings specifically in-office settings without fluoroscopy, CMS should establish that these procedures should be performed by only well-trained, qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Jimmy N. Ponder, Jr., MD, FIPP
One Day Surgery, L.L.C.
531-B Jefferson Terrace Blvd.
New Iberia, LA 70560
(337) 560-0880
(337) 560-0870 Fax

CMS-0
(74)

January 9, 2008

Mr. Kerry Weems
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: MS-1392-FC
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: MS-1392-FC

Dear Mr. Weems:

As a concerned interventional pain management physician I would like to comment on multiple disparities which exist between ASC setting and HOPD setting. These disparities and the CMS's new proposals and classifications will hinder patient access.

I am concerned about status indicator for CPT Codes 72285 and 72295 and non-payable issue which is related to discography. CMS pays separately for radiology portion of discography when it is performed independently in the HOPD setting, however it does not pay separately for the very same service when it is performed independently in the ASC setting. It was our understanding that in spite of significant cuts for interventional pain management the whole purpose was to apply the standards uniformly but it does not seem so. Discography procedures have two components: an injection portion that is reported by either CPT Code 62290 (Injection procedure for discography, in lumbar spine) or CPT Cod 62291 (Injection procedure for discography in cervical or thoracic spine), and a radiology portion that is reported by either CPT Code 72285 (discography interpretation and supervision in cervical spine) or CPT Code 72295 (discography interpretation and supervision in lumbar spine).

I believe that discography should be a separately payable service in the ASC as it is not treated as a surgical procedure eligible for separate payment under the payment system. This payment policy fails to recognize inequality between multiple settings and importance of these being done in an ASC setting.

The second issue relates to the update to the conversion factor while ASCs are facing losses, hospitals will still have an upper hand with a better update factor. This should be changed where both update factors are the same.

In addition, CMS should delay implementing the payment cap for office-based procedures. The present formula appears to be arbitrary.

To avoid exponential increases in procedures performed in all settings specifically in-office settings, CMS should establish that these procedures should be performed by only well-trained qualified physicians and in accredited office settings, thus creating an accreditation standard for offices to perform interventional procedures. This philosophy may be applied to other settings to simply reduce the overuse.

Thank you for the opportunity to comment on the Final Rule.

Sincerely,

Jon-Paul Harmer, M.D.

Lone Star Pain Medicine
907 E. Eureka, Ste B
Weatherford, TX 76086

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CORAR

Council on Radionuclides and Radiopharmaceuticals, Inc.

Henry H. Kramer, Ph.D., FACNP
Executive Director

3911 Campolindo Drive
Moraga, CA 94556-1551
(925) 283-1850
Fax: (925) 283-1850
E-mail: corar@silcon.com

JAN 30 2008

Via Hand Delivery and Email

January 28, 2008

Mr. Herb Kuhn
Deputy Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1932-FC
Comment on Radiopharmaceutical Payment in Final HOPPS Rule

Dear Mr. Kuhn:

On behalf of the Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR), I would like to thank you and your staff for meeting with CORAR on January 7, 2008 to discuss Medicare payment for radiopharmaceuticals under the hospital outpatient prospective payment system final rule (72 Fed. Reg. 66,580 (Nov. 27, 2007)).

This letter expresses our appreciation for your consideration during the meeting and serves as CORAR's comment on the final rule.

1. **CMS should restructure the tumor/infection imaging APCs to pay separately for certain high cost diagnostic radiopharmaceuticals or create composite APCs that are appropriately homogeneous in terms of clinical features and resources.**

Two radiopharmaceuticals (A9507 and A9565/A9572)[1] have mean costs of $1400 to $1700 (costs derived from CMS HOPPS data files). These two radiopharmaceuticals along with five/six other diagnostic radiopharmaceuticals have been bundled into newly configured APCs 406, 414, and 408 (Level I, II, and III Tumor/Infection Imaging) with 2008 payment rates at $322, $536 and $981. These payment rates are intended to cover the procedure and radiopharmaceutical costs for other radiopharmaceuticals with mean costs in the range of $400 to over $3000.

---

1 A9507 In 111 capromab per dose (Prostascint) used in the diagnosis of prostate cancer, A9565/A9572 In 111 petetreotide per dose (OctreoScan) used in the diagnosis of primary and metastatic neuroendocrine tumors.

The three newly configured tumor/infection imaging APCs combine tumor and infection imaging procedures. These procedures are not clinically similar. The new APCs also bundle many diagnostic radiopharmaceuticals with widely varying costs and dissimilar clinical uses. The resulting APCs are inconsistent with the basic requirement that APCs be homogeneous clinically and with respect to resources. See attached APC Analysis for HCPCS codes A9507 and A9565 which contrasts the APC payment rates with the median costs per claim and mean costs per dose for these two tumor agents and related procedures. CORAR supports CMS effort to develop appropriate payment bundles but strongly urges that a restructuring is needed for these APCs.

CORAR recommends that CMS implement one of the following:

a. Separate payment for all the diagnostic radiopharmaceuticals in APCs 406, 414, and 408,

b. Separate payment for radiopharmaceuticals A9507 and A9565/A9572 (the distinctly high cost radiopharmaceuticals)

c. Creation of separate composite APCs that bundle only tumor imaging procedures with the corresponding A9507 or A9565/A9572 radiopharmaceutical. A model of the logic flow chart for such composite APCs is attached along with a composite APC analysis chart of the associated data.

Furthermore, CMS has bundled into APCs 406, 414, and 408, special radiopharmaceuticals that are part of a therapeutic regimen: A9542 and A9544. As noted below, they should be paid separately.

2. CMS should recognize A9542 and A9544 as part of their therapeutic regimens.

A9542 and A9544[2] are the special dosimetric doses for the Zevalin and Bexxar therapeutic regimens, respectively. They are not diagnostic radiopharmaceuticals, but rather are a unique component to guide a larger therapy. FDA has not approved these products for separate use as diagnostic radiopharmaceuticals or otherwise, but rather, only as part of the therapeutic regimen.

Section 106 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 requires that CMS continue to pay for therapeutic radiopharmaceuticals based on hospital charges reduced to costs from January 1, 2008 through June 30, 2008. To implement the plain meaning as well as congressional intent, CMS should treat A9542 and A9544 as part of the class of therapeutic radiopharmaceuticals and continue payment based on hospital charges reduced to costs, as this methodology applied to both the dosimetric and therapeutic doses for these radioimmotherapeutic regimens in 2007.

CORAR recommends that CMS implement the changes proposed above effective January 1, 2008, or with the next quarterly update in HOPPS.

---

2 A9542 In 111 Ibritumomab per dose, A9544 I 131 Tositumomab per study dose

3. **CMS should accept alternate sources of data including manufacturers' estimates of average radiopharmaceutical prices when hospital charges under-report the appropriate prices.**

Certain radiopharmaceuticals still do not reflect accurate data from hospital reported charges. There continue to be serious problems in charge compression especially for higher cost radiopharmaceuticals. Moreover, many radiopharmaceuticals are compounded by nuclear pharmacies or hospitals from different components. The manufacturer of the "cold" kit, may not have pricing for the "hot" kit of the radiopharmaceutical. Nevertheless, new communications are developing between nuclear pharmacies and manufacturers to better enable the generation of more accurate data. Manufacturers may be able to obtain new pricing information about compounding costs, and component costs from some nuclear pharmacies. This may enable manufacturers to estimate the average price of the radiopharmaceutical to the hospital.

In the absence of hospital average acquisition cost, average price is the statutory alternative. For conventional drugs, average price can be based on conventional average sales price (ASP). Such ASP information does not exist for most radiopharmaceuticals, but average prices can be estimated in some cases. This is especially true for high cost, low volume radiopharmaceuticals.

CORAR urges that CMS remain open and utilize manufacturer reported average prices. Such estimated average prices will need to be validated and certified in ways that are appropriate for the unique circumstances of radiopharmaceuticals. This approach is fully within CMS's authority under Social Security Act §1833(t) which extends discretion to CMS to make necessary changes and adjustments in drug prices. Furthermore, where ASP is available, the Social Security Act §1833(t)(14)(A)(iii)(II) requires CMS to use ASP to base reimbursement for "specified covered outpatient drugs" (SCODs) as that term is defined in the Social Security Act §1833(t)(14)(B)(i). This reimbursement methodology has been recommended to CMS by both radioimmunotherapeutic regimen manufacturers. Therefore, where available, CMS should base payment for radioimmunotherapeutic regimens on manufacturer-reported ASP and also ensure that hospitals are reimbursed for the cost of nuclear pharmacy compounding.

CORAR welcomes and requests the further opportunity to meeting with CMS in February to discuss these proposals in greater detail. Gordon Schatz (202.414.9259) will contact Dr. Carol Bazell to arrange such a meeting.

Thank you for your consideration.

Sincerely,

Tamar Thompson

Tamar Thompson
Co-Chair, Clinical Practice and
Reimbursement Committee

Fred E. Longenecker

Fred E. Longenecker
Co-Chair, Clinical Practice and
Reimbursement Committee

Attachments
Cc: Carol M. Bazell, M.D.

c+a™ cleverley + associates

APC 406 408 414 - Analysis by Diagnostic Radiopharmaceutical

Note 1: CMS prohibits the release of small cell sizes. Rows with counts < 11 are suppressed from this data release.

Note 2: This analysis uses the CMS single/multiple logic, but does not include any trimming of cost values.

APC	Definition	2008 Payment
APC 0406	Level I Tumor/Infection Imaging	$ 322.81

			Total Cost Per Claim				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Psuedo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A4641	Diagnostic imaging agent	186	631.46	86.69	3,482.38	504.24	23.4%	1.7%	88.6%	19.2%
A9500	Tc-99m sestamibi, up to 40 mCi	565	338.46	51.19	3,092.93	257.81	26.5%	3.8%	95.0%	27.2%
A9507	In-111 capromab pendetide, up to 10 mCi	12	1,571.92	507.67	3,256.58	1,317.73	71.2%	49.7%	93.3%	77.8%
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	53	532.60	147.24	1,910.18	284.01	47.8%	11.6%	97.0%	35.9%
A9521	Technetium Tc-99m exametazine, up to 25 mCi	27	523.73	406.87	1,550.35	408.52	62.0%	47.6%	79.6%	59.4%
A9528	I-131 sodium iodide capsule(s) per mCi	1,572	501.46	53.09	6,164.50	369.29	20.1%	0.6%	98.1%	16.1%
A9544	I-131 tositumomab, dx; per dose	13	426.40	264.51	833.49	286.80	30.3%	5.4%	81.6%	6.6%
A9556	Ga-67 gallium citrate, per mCi	163	342.26	91.14	1,375.19	288.04	33.9%	1.8%	79.6%	30.2%
A9565	In-111 pentetreotide, per mCi	145	1,261.58	115.41	4,755.37	946.31	74.3%	23.8%	96.9%	79.2%

APC	Definition	2008 Payment
0408	Level III Tumor/Infection Imaging	$ 981.10

			Total Cost Per Claim				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Psuedo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A4641	Diagnostic imaging agent	99	1,302.34	103.36	8,023.57	1,085.74	60.6%	0.6%	91.4%	67.8%

A9500	Tc-99m sestamibi, up to 40 mCi	193	479.20	148.24	1,455.92	410.97	24.5%	4.1%	44.4%	24.8%
A9507	In-111 capromab pendetide, up to 10 mCi	501	1,467.66	377.43	10,270.48	1,210.42	70.9%	19.3%	97.9%	74.2%
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	105	1,338.45	49.20	5,452.58	1,158.39	66.9%	38.1%	95.9%	67.8%
A9528	I-131 sodium iodide capsule(s) per mCi	22	587.45	177.16	1,455.96	562.60	25.1%	3.2%	43.7%	29.8%
A9542	In-111 ibritumomab, dx, up to 5 mCi	150	3,354.55	309.97	28,165.30	2,129.75	65.5%	6.8%	94.9%	73.0%
A9544	I-131 tositumomab, dx, per dose	46	1,896.19	960.92	6,059.95	1,513.25	68.9%	26.2%	91.1%	68.0%
A9547	In-111 oxyquinoline, dx, per 0.5 mCi	18	560.94	354.20	1,117.69	518.56	46.1%	6.8%	67.5%	49.5%
A9556	Ga-67 gallium citrate, per mCi	187	547.98	128.68	2,223.11	443.44	21.7%	1.2%	72.1%	16.8%
A9565	In-111 pentetreotide, per mCi	938	2,044.69	148.06	16,309.12	1,196.44	65.0%	0.5%	98.3%	66.8%

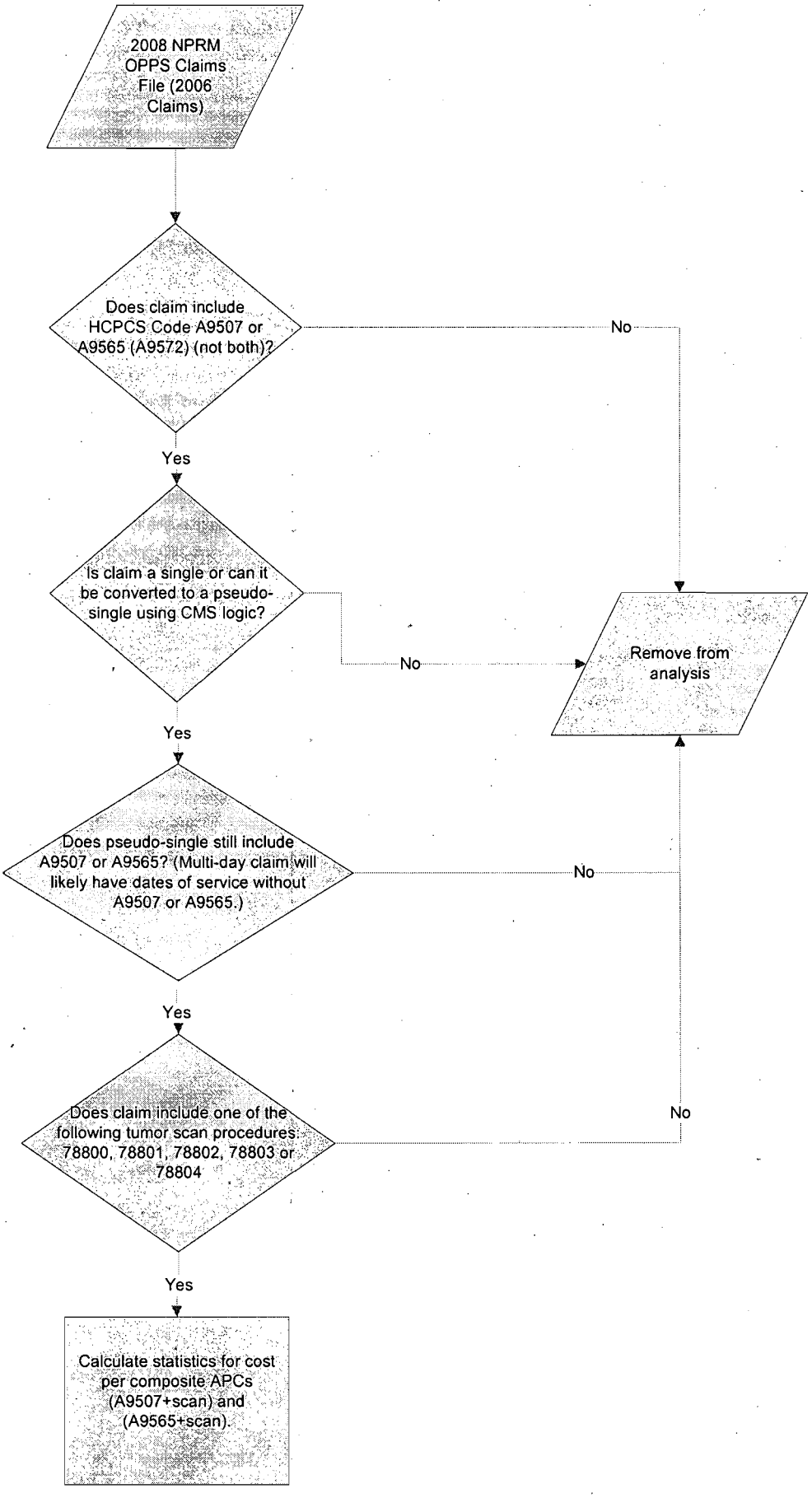
APC	Definition	2008 Payment								
0414	Level II Tumor/Infection Imaging	$ 536.15	Total Cost Per Claim				Percent of Diagnostic Radiopharmaceutical Cost			
Diagnostic Radiopharm	Definition	Single /Psuedo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
A4641	Diagnostic imaging agent	691	733.21	145.10	3,627.52	637.80	53.3%	1.4%	91.9%	56.9%
A9500	Tc-99m sestamibi, up to 40 mCi	19	356.26	140.06	606.44	332.37	38.9%	2.8%	71.7%	34.3%
A9507	In-111 capromab pendetide, up to 10 mCi	156	1,358.62	309.71	3,599.77	1,233.65	70.6%	7.5%	91.4%	74.8%
A9508	Iodine I-131 iobenguane sulfate, per 0.5 mCi	97	1,262.12	284.47	7,368.64	877.12	63.9%	6.0%	94.3%	70.8%
A9521	Technetium Tc-99m exametazine, up to 25 mCi	3,499	663.79	93.85	11,795.14	553.03	54.7%	4.1%	98.3%	55.9%
A9528	I-131 sodium iodide capsule(s) per mCi	23	393.44	206.33	705.45	392.57	27.9%	6.3%	84.8%	29.3%
A9542	In-111 ibritumomab, dx, up to 5 mCi	106	2,303.86	259.92	11,330.49	1,533.46	67.3%	9.8%	95.0%	73.4%
A9547	In-111 oxyquinoline, dx, per 0.5 mCi	2,704	670.80	102.54	6,362.30	564.48	52.8%	1.6%	97.0%	53.4%
A9556	Ga-67 gallium citrate, per mCi	1,354	399.60	66.78	6,624.03	332.33	24.3%	0.4%	89.7%	22.5%
A9565	In-111 pentetreotide, per mCi	600	1,401.61	62.74	13,071.21	1,048.47	65.7%	6.1%	97.9%	70.4%

Simulation Summary - Based on NPRM Claims File and Final Rule Logic (must have RP present)

APC	Definition	Single /Psuedo Single Claims	Mean Cost per Claim	Minimum Cost per Claim	Maximum Cost per Claim	Median Cost per Claim
0406	Level I Tumor/Infection Imaging	8,399	501.83	15.43	28,837.80	324.72
0408	Level III Tumor/Infection Imaging	3,204	1,323.79	29.10	28,165.30	821.06
0414	Level II Tumor/Infection Imaging	11,613	674.81	19.72	36,691.96	514.43

CMS Median Cost File Statistics - Based on Final Rule Claims File and Final Rule Logic						
APC	Definition	Single Frequency	Mean Cost	Minimum Cost	Maximum Cost	"True" Median Cost
0406	Level I Tumor/Infection Imaging	9,167	336.94	40.08	3,520.11	268.54
0408	Level III Tumor/Infection Imaging	4,234	944.95	45.60	11,646.93	614.64
0414	Level II Tumor/Infection Imaging	13,121	574.48	40.16	6,268.76	463.43

In-111 (A9507, A9565) + Tumor Scan Composite APC Logic



AMERICAN ASSOCIATION FOR PEDIATRIC OPHTHALMOLOGY AND STRABISMUS

January 28, 2008

Mr. Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: 42 CFR Parts 410, 411,412, et al. Medicare and Medicaid Programs; Interim and Final Rule. ASC payment for 68816, Probing of nasolacrimal duct, with or without irrigation; with balloon catheter dilation.

Dear Acting Administrator Weems:

The American Association for Pediatric Ophthalmology and Strabismus (AAPOS), representing over 1200 ophthalmologists who provide medical and surgical eye care for children, is writing to share our comments regarding the proposed ASC payment for CPT 68816. AAPOS members perform probing of the nasolacrimal duct in children with transluminal balloon catheter dilation. These services are most commonly rendered under general anesthesia. This requires the procedure to be performed either in an Ambulatory Surgery Center Operating Room or Hospital Operating Room. This procedure is not performed on children in an office setting.

CMS has identified this service in a recent memorandum, "New CY 2008 ASC covered surgical procedures assigned temporary office-based payment indicators on an interim final basis," as most commonly performed in the office, making the facility payment the office rate. Though CMS does not pay for the care of most children, this decision will effectively drive the service out of the ASC and into the Hospital where it will dramatically increase costs of care of children. Furthermore we are not aware of this procedure being commonly performed in the office setting even among adult beneficiaries because of associated discomfort. The hospital payment rate for CPT 68816 is proposed to be $1193.03. Since the procedure is not principally performed in the office, it should be eligible for payment based upon the appropriate percentage of the OPPS rate of $1193.03. AAPOS respectfully requests that this change be made prior to implementation.

Thank you for the opportunity to comment.

Sincerely,

Edward Buckley, M.D.
President

Headquarters/Annual Meeting
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AAPOS 34th Annual Meeting
April 2-6, 2008
Washington, DC

AAPOS 35th Annual Meeting
April 17-21, 2009
San Francisco, CA

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COMPREHENSIVE OPTOMETRY
Alan D. Brown, O.D.

OCULOPLASTIC SPECIALIST
Kenneth R. Neufeld, M.D.

1/21/2008

Center for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1392-FC Mail Stop C4-26-04
7500 Security Boulevard
Baltimore, MD 21244-1850

To Whom It May Concern:

This letter is in regard to the ambulatory surgery center payment level for CPT code 68816. It has been brought to my attention that the proposed payment for ambulatory surgery center reimbursement for CPT code 68816 is to be changed. It is wonderful that a new code was developed for this excellent procedure. Code 68816 describes balloon dilation of the nasolacrimal duct. This is a revolutionary procedure for treating tear duct obstruction that has been around for at least for the past 10 to 12 years. In the past, children who underwent nasolacrimal duct probing and did not have a successful outcome had to undergo placement of silicone tubes in the tear ducts, which stayed for six months. Since balloon dilation has been introduced, the incidence of using these tubes to hold the tear duct system open has dropped dramatically.

The fact of the matter is that doing a Lacricath balloon procedure is just as technically difficult as putting in the silicone tubes. Balloon dilation and nasolacrimal duct has never been an office procedure for children. This is a procedure performed in the operating room under general anesthesia requiring as much time and clinical confidence as placing silicone tubes. To adjust the code to a level commensurate with an office setting procedure is inappropriate.

This excellent procedure has become the procedure of choice when children fail probing. It is uncalled-for it to be performed in an office setting due to the discomfort, pain, and risk involved. I appreciate your attention to this matter and please feel free to contact me with any questions.

Sincerely,

Stephen N. Lipsky, MD, FAAP, FACS
SNL/sba/phy/srw **DD:** 1/21/2008 **DT:** 1/22/2008

Cellphone #: (678) 517-6846

ACS

ACS-18660

January 25, 2008

Centers for Medicare & Medical Services
Karen Turdel
Deputy Director
HIPAA Enforcement
Attn: Office of E Health Standards and Services
P.O. Box 8030
Baltimore, MD 21244-8030

Re: HIPPA Complaint-07TCSO1980.doc
Thru: Brenda Allen-Coleman

Reference Number: 07TCS01980

Dear Ms. Trudel:

This letter is in response to the allegation complaint letter dated December 27, 2008, reference number 07TCS01980. Please see allegation(s) and response to the allegation(s) and /or any remediation or explanation.

Allegation: The complaint alleges that when a claim is submitted on paper, Mississippi Medicaid is reporting 0 as the patient control number in data element CLP010f the Health Care Claim Payment / Advice (835) transaction. Per the ASC X12N 835 Implementation Guide, the patient control number reported on the claim must be reported in CLP01 of the 835 file. Without this information the provider cannot rely on the 835 for auto posting of all payments reported in the 835, causing manual posting of these accounts.

ACS Response: Based on the patient control number issue described in the CMS letter. Our research indicates the following:

- We do accept the patient control number on paper claims.
- The patient control number is populated on the outbound 835 transaction when present.
- The only time we would not accept a patient control number on a paper claim is when the value submitted on the actual paper claim is not legible.
- This is not a required field for our claims adjudication process, the claim is processed as is and not returned to the provider.

If there are still concerns that the patient control number is not being accepted and transmitted in the outbound 835. Please provide specific examples and we would be happy to research those in detail.

Sincerely,

Doug Tomlin
Executive Account Manager
ACS Government Healthcare Solutions
Mississippi Fiscal Agent Services

56

JAN 28 2008

SCA
Surgical Care Affiliates

January 28, 2008

VIA HAND DELIVERY

Kerry Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1392-FC
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1392-FC - Medicare Program: Changes to the Hospital Outpatient Prospective Payment system and CY 2008 Payment Rates, the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates, the Hospital Inpatient Prospective Payment System and FY 2008 Payment Rates; and Payments for Graduate Medical Education for Affiliated Teaching Hospitals in Certain Emergency Situations

Dear Acting Administrator Weems:

On behalf of Surgical Care Affiliates, please accept the following comments regarding this rule, which, among other items, sets forth payment classifications for HCPCS codes for ambulatory surgical centers (ASCs). 72 Fed. Reg. at 66579 (November 27, 2007). We appreciate the work that has gone into establishing the payment classifications on a code-by-code basis.

With interests in 131 ASCs in 33 states, Surgical Care Affiliates is one of the largest operators of ASCs in the United States. ASCs offer outpatient surgery in a convenient, safe environment characterized by superior patient care.

I. ASC Payment Indicators for HCPCS Codes with Comment Indicator "NI"

While we generally support the ASC payment indicators CMS has designated for HCPCS codes assigned a comment indicator of "NI", we believe the payment indicator assignments for certain of the HCPCS codes under comment should be reconsidered. In particular, we draw your attention to the following procedures:

HCPCS Code 21073: The newly created CPT code 21073, Manipulation of temporomandibular joint(s), therapeutic, requiring an anesthesia service (i.e., general or

monitored anesthesia care), has been assigned a payment indicator of P3. This assignment assumes that this procedure meets the criteria CMS has set forth for designating services as office based, namely that Medicare physician claims data show the service is rendered more than 50 percent of the time in the physician office setting (see 72 FR beginning at 42509). In this case, we do not believe the criteria CMS established have been met, as there is no existing claims data that would allow the agency to determine the service has been rendered more than 50 percent of the time in the physician office setting. Moreover, this new code is not analogous, or essentially equivalent, to a previously existing code. As a result, there is no existing data that may be used as a proxy for demonstrating site of service patterns (as might be true in cases in which the AMA deletes a given code and replaces it with another code which has an identical descriptor for purposes of improving the organization of the CPT manual). Particularly because the office-based designation is a permanent one, we believe the agency bears a burden of proof in categorizing any service as office-based under its new policies.

Further, CPT code 21073, by definition, may only be reported when anesthesia services such as general anesthesia and monitored anesthesia care have been necessary to perform the therapeutic manipulation. We believe it is unlikely that physician offices, which do not commonly provide these anesthesia services, will be the primary site of this service.

We also note that other similar surgical services that include a requirement for anesthesia have all been assigned a payment indicator of either A2 or G2. These include the following: CPT code 23700, Manipulation under anesthesia, shoulder joint, including application of fixation apparatus; CPT code 24300, Manipulation, elbow, under anesthesia; CPT code 25259, Manipulation, wrist, under anesthesia; CPT code 26340, Manipulation, finger joint, under anesthesia, each joint; CPT code 27275, Manipulation, hip joint, requiring general anesthesia; and CPT code 27570, Manipulation of knee joint under general anesthesia.

For the above reasons, CMS should reconsider the interim assignment of a P3 payment indicator to CPT code 21073. We believe a payment indicator of G2 is the appropriate assignment.

HCPCS Code 68816: The newly created CPT code 68816, Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation, has also been assigned a payment indicator of P3. While this is a newly created CPT code, the American Medical Association (AMA) has indicated that it is most closely related to existing CPT code 68815. Specifically, the AMA stated, in their publication *CPT Changes 2008: An Insider's View*, "The code previously used to identify this procedure, code 68815, Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia, was inadequate."

We have reviewed the CMS data file for 2006 showing the numbers of allowed services for the hospital outpatient, ambulatory surgical center and physician office setting for CPT code 68815 and found that 68815 was not performed 50 percent of more of the time in the physician office setting.

In light of this information, we believe that the payment indicator for code 68816 should be changed to G2.

II. Newly Created HCPCS Code Not Included for ASC Coverage in 2008

The newly created CPT code 52649, Prostate laser enucleation is covered under the OPPS for 2008, but was not included for ASC coverage in Addendum AA. This procedure, commonly referred to as holmium laser enucleation of the prostate (or HoLEP), is similar to CPT code 52647, Laser surgery of prostate and CPT code 52648, Laser surgery of prostate. Both codes 52647 and 52648 were covered under the original ASC payment system and remain included for coverage under the revised ASC payment system. A study of HoLEP by Aho et al (see J Urol. 2005 Jul;174(1):210-4.) describes a mean hospital time of 13.7 hours, which could readily be accommodated in the ASC setting under current CMS policies. An additional HoLEP study by Kuo et al (see World J Surg Oncol. 2003 Jun 6;1(1):6.) confirms that the procedure may be performed as either an outpatient or overnight procedure depending on patient preference.

Based on this information, we request CMS add CPT code 52649 to the listed of covered surgical procedures in Addendum AA for 2008.

III. Additional Comments Regarding the Revised ASC Payment System

While we support many of the policies CMS has implemented in its revision of the ASC payment system, ASCs still face certain significant barriers to providing a full range of surgical services to Medicare beneficiaries. These obstacles not only limit access to selected services, but also limit the savings that might otherwise have accrued to both the Medicare program and its beneficiaries. In particular, we draw your attention to the following issues:

ASC payment for covered surgical services involving devices and biologicals: Many ASCs are interested in offering covered surgical services involving devices and biologicals to Medicare beneficiaries, but are finding that the revised payment policies result in reimbursement that is not sufficient to cover costs. This is true both for services for which reimbursement is determined according to the standard ASC methodology and also for services for which reimbursement is determined according to the adjusted methodology for device-intensive procedures.

For example, the reimbursement for CPT 57288, Repair bladder defect, is calculated according to the standard ASC methodology. The national payment amount for 2008 is $979.81. The cost of the sling is $1095.00 (Johnson & Johnson, Gynecare TVT Secur®), which exceeds the 2008 reimbursement established for the procedure and the implant. Moving immediately to the fully implemented payment amount may allow this procedure to become economically feasible for ASCs now, rather than years from now.

An additional example of a device-dependent procedure with reimbursement insufficient to cover costs is CPT code 63685, Insert/redo spinal neurostimulator pulse generator. Despite having been designated as a device-intensive procedure under the revised ASC payment system, and therefore having had special allowance made for device cost as estimated by CMS, the 2008 national reimbursement amount of $13,727.20 is inadequate. The pulse generator alone has an invoice cost of $14,760 (Advanced Bionics Corporation, Precision Implantable Pulse Generator).

Even when this procedure is fully transitioned in 2011 with an estimated national reimbursement amount of $14,524.72, the reimbursement will not cover the cost of the pulse generator alone. We believe the policy CMS has established for device-intensive procedures should be modified in a manner that takes into account the differences between hospital and ASC device costs.

In order to allow access to these services in the ASC setting, CMS should consider modifying its current policies. Options would include: 1) allowing full payment to ASCs for the device portion of any device dependent APC, regardless of the percentage the device represents in relation to the total APC reimbursement; 2) moving to a fully implemented payment amount for procedures previously covered under the ASC benefit that require implanted devices or biologicals; and 3) allowing reimbursement for implanted biologicals on a reasonable cost basis or invoice amount, as is currently the case for corneal tissue. As stated previously, establishing policies that allow adequate reimbursement rates for ASCs ultimately results in savings both to the Medicare program and its beneficiaries as compared to the generally more costly HOPD setting.

ASC conversion factor: As we have stated in previous comments, we believe the estimated 15% migration of services from the physician office to the ASC is significantly overstated. Our facilities have little interest in using their specialized physical plant, personnel, and equipment to perform minor procedures on a routine basis for reimbursement that is below cost, and physicians have no reason to move cases from the office to the ASC setting unless it is medically necessary to do so. Using more reasonable migration assumptions would result in a more appropriate ASC conversion factor. We continue to encourage CMS to revisit its migration assumptions and evaluate their accuracy when data becomes available.

Coverage policies for ASCs: We remain very concerned by the definition of overnight stay CMS has adopted. From a clinical standpoint, it would be much more appropriate to define a length of stay. Further, the use of midnight as the equivalent of overnight is not only counter to previous CMS statements on this matter, which defined an overnight stay as a stay of less than 24 hours in duration, but also at odds with numerous state regulations. We also remain concerned about the exclusion of unlisted surgical procedure codes from ASC payment under the revised ASC payment system. This policy, in addition to being incongruent with the approach CMS takes to reimbursement of unlisted codes under OPPS, is unnecessarily restrictive.

Surgical services packaged into radiologic services: With the implementation of the expanded packaging policies under OPPS, even more procedures safely performed in the ASC setting have been packaged with services outside the CPT surgical range (CPT 10000-69999). Procedures that had been (or would otherwise be) eligible for payment in the ASC are now newly ineligible because of a change in OPPS packaging policy, not because there has been a determination that the procedure is unsafe in the ASC.

Specifically, current policy creates barriers to performing selected services that meet CMS's definition of ASC surgical services (CPTs 10000-69999). Procedures such as arthrography, diskography and epidurography have both a surgical injection component and a radiographic component. In CPT, the injection portion of the service is described by a code in

the surgical range (in the case of diskography, 62290 or 62291), while the radiographic portion of the service is described by a code in the radiology range (in the case of diskography, 72285 and 72295). Under OPPS, the injection portion of the procedure is packaged into the radiographic portion of the procedure. As a result, only CPT codes 72285 and 72295 are payable.

Although CMS has adopted policies that will allow ASCs to bill for selected radiology services as ancillary services when provided integral to the surgical service under the revised ASC payment system, the codes for radiology services that package a surgical service have not been designated as separately payable. CMS has stated that it sees no rationale for offering separate payment for the surgical portion of these services. However, the surgical service is a necessary precedent to the radiologic service in these cases and the radiologic service cannot be properly performed in absence of the surgical injection procedure. Therefore, we request that the agency outline an alternative approach for ASC providers who wish to offer these surgical services to Medicare beneficiaries. One of the predominant trends in today's clinical practice is the integration of multiple disciplines and modalities to streamline patient care. These integrated care processes enhance efficiency and quality. However, payment policies that view these services in separates silos can disrupt these interrelationships and limit beneficiary access to efficiently integrated services, particularly in the ASC setting.

ASC wage index: We have reviewed both the proposed and final rules for the revised ASC payment system (CMS-1517-F and CMS-1392-P) and have not found reference to excluding the occupational mix adjustment from the ASC wage index. It was our understanding that CMS intended to "apply to ASC payments under the revised ASC payment system the IPPS pre-reclassification wage index values associated with the June 2003 OMB geographic localities, as recognized under the IPPS and OPPS, in order to adjust national ASC payment rates for geographic wage differences under the revised payment system" (see CMS-1517-F, p 42547 of the August 2, 2007, Federal Register). Removing the occupational mix adjustment from the ASC wage index re-introduces variation in the geographic adjustment completely unrelated to the ASC industry. We request CMS describe its rationale for having two different geographic adjustment factors for providers in the same market in future rulemaking.

ASC adjustment for inflation: ASC adjustments for inflation should be made using the hospital market basket rather than the CPI-U. The CPI-U is a measure of consumer inflation and its inputs do not reflect the items and services that ASCs must purchase in order to provide care for their patients. On the other hand, the hospital market basket is based on expense categories that are shared by both hospitals and ASCs. Given that CMS is not bound by statute to use the CPI-U to adjust ASC payments for inflation, the agency should adopt the hospital market basket for ASC updates, recognizing the similar resource requirements and inflationary pressures facing ASCs and HOPDs.

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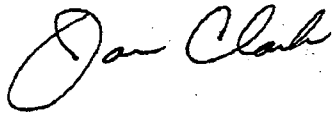
Thank you for considering these comments. We appreciate the opportunity to share our views on the payment indicator designations and other issues pertinent to the revised ASC payment system.

Sincerely,



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Re: CMS-1392-FC (Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates) – Changes to Packaged Services (Diagnostic Radiopharmaceuticals; Payment for Drugs and Biologicals without Pass-Through Status That Are Not Packaged (Payment for Radiopharmaceuticals).

Dear Administrator Weems:

Cell Therapeutics, Inc. (CTI), a biotechnology company committed to developing and delivering innovative treatments for cancer, submits the following comments on the Centers for Medicare & Medicaid Services' (CMS) final rule with comment period regarding changes to the hospital outpatient prospective payment system (OPPS) and 2008 payment rates.[1] In these comments, we address provisions of the Final Rule that relate to payment for Zevalin® (ibritumomab tiuxetan).

Summary

CTI acquired the marketing, sales, and development rights to Zevalin in December 2007 from Biogen Idec. Zevalin is an anti-cancer regimen for patients with relapsed or refractory low-grade, follicular, or transformed B-cell non-Hodgkin's lymphomas (NHL), including patients with rituximab-refractory follicular NHL. This therapy regimen can often be the last option for patients who are not responding to other treatments. Since FDA approval, Zevalin has had significant Medicare reimbursement challenges due to its classification by CMS as a radiopharmaceutical. Zevalin was approved by the FDA under a Biologics License Application. As discussed below, CTI respectfully requests that CMS classify Zevalin as a biological and pay for the treatment under the Average Sales Price (ASP) methodology.

The payment methodology for Zevalin in the 2008 Final Rule would significantly threaten beneficiary access to this critical therapy and could result in some centers closing their

[1] 72 Fed. Reg. 66,580 (November 27, 2007).

costs for the first six months of 2008. We look forward to working with CMS to determine an appropriate permanent payment methodology in 2009 and future years.

Background on Zevalin

Zevalin is in a class of biologics known as radioimmunotherapeutics. These products use biologically produced, highly specific, targeted proteins called monoclonal antibodies that bind to molecules expressed on cancer cells. By attaching a radioactive isotope to the antibody, radioimmunotherapeutics can deliver highly effective doses of radiation directly to cancer cells while minimizing the exposure of normal tissues to damaging radiation.

The Biologics License Application (BLA) for Zevalin was approved by the FDA's Center for Biologics Evaluation and Research on February 19, 2002. Zevalin was granted accelerated approval by the FDA, and the FDA press release noted that this "novel treatment regime" would provide another treatment option for NHL patients, in whom the antitumor effectiveness and duration of tumor responses to standard treatments diminishes after relapse following initial therapy.

The full FDA-approved Zevalin therapeutic regimen consists of two components: an initial *biodistribution dose*, followed by a *therapeutic dose*. The two doses use the same monoclonal antibody (ibritumomab tiuxetan), but different radioactive isotopes. The biodistribution dose uses indium-111 (In-111), while the therapeutic dose uses yttrium-90 (Y-90). These two distinct steps are inseparable parts of a therapeutic regimen as required by the FDA and outlined in product labeling.

In order to assure that the treatment regimen is safe and effective in a patient, the physician must first image the biodistribution – the body's uptake – of the monoclonal antibody. The therapeutic Y-90 radioisotope does not emit gamma radiation, and cannot be used for imaging purposes. Instead, physicians use the In-111 radioisotope – a gamma emitter – attached to the same monoclonal antibody for the biodistribution dose, allowing the necessary imaging. Because the purpose of the biodistribution dose is to ensure the safety of the therapeutic dose, it is critical that the same monoclonal antibody be used for both doses. Y-90 Zevalin is not administered to patients with altered biodistribution, as determined by imaging with In-111 Zevalin. After the physician confirms that the patient has acceptable biodistribution, the therapeutic dose of Zevalin is administered using weight-based dosing. This dose delivers the Y-90 isotope to directly attack the lymphoma.

Clinical Benefits of Zevalin

Zevalin is among the few treatment options that can produce long-term disease-free survival in some patients with relapsed indolent non-Hodgkin's lymphoma who no longer respond to conventional chemotherapy and the monoclonal antibody, rituximab. Zevalin thus represents an important treatment option for these lymphoma patients, and provides benefits that are distinct from those of other approved therapies.

The complete Zevalin therapeutic regimen is administered as two ten-minute infusions approximately one week apart. In view of the palliative nature of therapy for patients with

relapsed or refractory indolent lymphoma, the Zevalin regimen represents a far less burdensome therapy than repeated cycles of chemotherapy.

Prior Hospital Outpatient Payment for Zevalin

The reimbursement challenges for Zevalin are illustrated by the fact that the payment methodology has changed almost yearly since its approval. These changes are summarized in the below chart, followed by a history of Medicare payment for Zevalin.

Historical Medicare Hospital Outpatient Payment for Zevalin

Year	Methodology	Rate	
2002 (through September 30)	Miscellaneous J-Code	No separate payment; charges may trigger outlier payments	
2002 (after October 1)	Outpatient new technology transitional pass-through payment	78% of AWP (pass through pro rata reduction) Approximately $21,959	
2003	New Technology APC	In-111 Y-90 Total	$2,750 $20,000 $22,750
2004 (proposed)	External data	In-111 Y-90 Total	$2,260 $19,565 $21,825
2004 (MMA)	88% of AWP	In-111 Y-90 Total	$2,565 $22,210 $24,775
2005	83% of AWP	In-111 Y-90 Total	$2,419 $20,948 $23,367
2005 GAO Report	Survey	Y-90	$19,615
2006	Individual charges reduced to costs	Varied by claim	
2007	Charges reduced to costs	Varied by claim	
2008 OPPS Final Rule	In-111 packaged Y-90 at median cost	In-111 Y-90	Packaged $15,024
2008 Medicare Legislation (Jan-Jun)	Charges reduced to costs	Varies by claim	

When Zevalin first received FDA-approval, it was temporarily paid as a biologic under the transitional pass-through payment category. However, the decision in the 2003 OPPS Final Rule to classify Zevalin as a radiopharmaceutical prevented Zevalin from being eligible for the pass-through payment. Instead, both doses of Zevalin were paid under New Technology APCs.

Before the passage of the Medicare Modernization Act (MMA), CMS published the 2004 Hospital Outpatient Final Rule, which used "verifiable data" from external sources to establish a payment rate for Zevalin.

However, the MMA, signed in December 2003, required that radiopharmaceuticals, including Zevalin, be paid as a "specified covered outpatient drug." In 2004, the MMA required payment at a minimum of 88% of AWP, slightly raising the payment from the rate set by CMS. In 2005, the payment rate was again set at the statutory floor of 83% of AWP.

In subsequent years, the MMA required CMS to establish payment for specified covered outpatient drugs at "the average acquisition cost for the drug for that year . . . as determined by the Secretary taking into account the hospital acquisition cost survey data [collected by the Government Accountability Office (GAO) and the Secretary]."[2] In July 2005, the GAO published a survey of radiopharmaceutical purchase prices for CMS consideration in rate-setting.[3] The GAO report listed a cost for Zevalin that was almost identical to the rate determined by CMS in the 2004 Final Rule (before the passage of the MMA).

In its 2006 Hospital Outpatient Rule, CMS established a payment policy for separately payable radiopharmaceuticals, including Zevalin, that based payment on the hospital-reported charge for the radiopharmaceutical reduced to cost using hospital-specific overall cost-to-charge ratios (CCR). This resulted in a newly calculated payment for each claim submitted for a separately payable radiopharmaceutical, based on the reported charge on the claim.

CMS believed that this methodology provided the "best available proxy for the average acquisition cost" because "hospitals can appropriately adjust their charges for radiopharmaceuticals so that the calculated costs properly reflect their actual costs," and instructed that "it is appropriate for hospitals to set charges for these agents in CY 2006 based on all costs associated with the acquisition, preparation, and handling of these products so that their payments under the OPPS can accurately reflect all of the actual costs associated with providing these products to hospital outpatients."

After considering several alternative methodologies, the 2007 Final Rule maintained the 2006 methodology. CMS repeated its conclusion that these rates represented the best proxies for average acquisition cost.

CY 2008 OPPS Final Rule Regarding Payment for Zevalin

As written, the 2008 Final Rule would further exacerbate the reimbursement challenges. First, the CMS policy to set rates for therapeutic radiopharmaceuticals based on mean unit costs from CY 2007 data claims will reduce payment for the Zevalin therapeutic dose to well below the average acquisition cost of the drug. Second, the CMS policy to package payment for the biodistribution dose will eliminate payment for providers who administer this therapy by setting payment below actual costs. These policies are based on the CMS classification of Zevalin as a radiopharmaceutical.

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[2] Social Security Act § 1833(t)(14).

[3] Government Accountability Office, "Hospital Radiopharmaceutical Prices." GAO-05-733R (July 14, 2005).

In the 2008 Final Rule, CMS classifies the In-111 of Zevalin as a "diagnostic radiopharmaceutical" and the Y-90 as a "therapeutic radiopharmaceutical." CTI is concerned that CMS' proposed reimbursement methodology for these two classes of drugs would limit Medicare beneficiaries' access to Zevalin. In particular, we believe that packaging payment for In-111 Zevalin and the rate-setting methodology for Y-90 Zevalin will result in inaccurate and insufficient payment for these unique therapies. We believe these proposals are inconsistent with the statutory requirement that payment should be based on acquisition costs, subject to any adjustments for overhead costs.

The CY 2008 payment rate for Y-90 Zevalin and other "therapeutic radiopharmaceuticals" is based on an estimate of mean costs derived from the CY 2006 claims data. The payment rate is calculated using the standard methodology of applying departmental specific cost-to-charge ratios (or the overall cost-to-charge ratio (CCR) if a departmental CCR is not available) to determine mean costs based on claims data. Payment for In-111 Zevalin and other "diagnostic radiopharmaceuticals" is packaged into the associated procedure. Both of these methodologies will reduce payment below actual product costs, even before considering overhead and procedure costs.

The CY 2008 payment rate for Y-90 Zevalin is $15,023.91, 23 percent less than the purchase price determined by the GAO in 2005[4] and well below the current list price of $25,238. GAO concluded that its survey resulted in acquisition cost estimates that were "sufficiently accurate for use in developing Medicare rates." CMS has not conducted surveys of hospital acquisition costs since the 2005 GAO report. Moreover, the Final Rule notes that the practice of hospital charge compression can result in inappropriately low payment for high cost items when rates are based on average costs using hospital CCRs. These factors suggest that the 2008 Final Rule payment rate is inappropriately low for Zevalin, and does not reflect the average acquisition cost.

The payment for In-111 Zevalin will be packaged in the procedure rate for the diagnostic service. A review of the CY 2006 Medicare cost data indicates that claims for In-111 Zevalin appear in several APCs. However, the majority of the In-111 Zevalin claims are found in APC 414 (Level II Tumor/Infection Imaging), which will have a payment rate of $536 – just 20 percent of the acquisition cost of $2,598.[5] Some In-111 Zevalin claims are found in APC 408 (Level III Tumor/Infection Imaging) which will be paid at $981 – 37 percent of the average acquisition cost.

Comparison of 2008 Hospital Outpatient Payment for Zevalin to Estimated Average Acquisition Cost

	In-111 Zevalin	Y-90 Zevalin	Combined
CY 2008 Payment Rate	$981*	$15,024	$16,005
Estimated Average Acquisition Cost	$2,598**	$19,615***	$22,213

[4] Government Accountability Office, "Hospital Radiopharmaceutical Prices." GAO-05-733R (July 14, 2005). The report is based on a survey of hospital-reported prices between July 2003 and June 2004.
[5] Society of Nuclear Medicine Preliminary Data (reflecting 2006 prices).

2008 payment as percentage of Estimated Average Acquisition Cost	37%	76%	72%

* Maximum payment, based on APC 408 (Level III Tumor/Infection Imaging), not accounting for overhead costs or procedure costs. APC 414 (Level II Tumor/Infection Imaging) has a payment rate of $536.
** Based on Society of Nuclear Medicine Survey
*** Based on 2005 GAO Survey

Legislative Modification to Payment for Radiopharmaceuticals

On December 29, 2007, the Medicare, Medicaid, and SCHIP Extension Act of 2007 was signed into law. Section 106 of the Act sets payment for certain radiopharmaceuticals at charges reduced to cost (amending § 1833 of the Social Security Act to include these products).

The legislation was designed to address concerns that insufficient reimbursement for radioimmunotherapies like Zevalin would lead to diminished access for beneficiaries. The text of the law extends the payment methodology to "therapeutic radiopharmaceuticals." It is our understanding that CMS reads this provision to only extend to the Y-90 component. CTI believes that it was Congress's intention to include *all* of the elements of the FDA-approved Zevalin radioimmunotherapeutic regimen within the scope of this language. We believe that Congress included this provision in order to address the well-documented disparity between the cost of radioimmunotherapies and the reimbursement rates proposed for 2008 by CMS.

The FDA-approved label for Zevalin specifically notes that "In-111 Ibritumomab Tiuxetan and Y-90 Ibritumomab Tiuxetan are components of the Zevalin therapeutic regimen." The label covers kits for the preparation of the two doses, and FDA treats the two doses as part of the same product. Moreover, both doses of Zevalin were included on a single BLA, and FDA approved both doses as part of a single approval letter and license. Based on this history at the FDA – including the most recent label supplement in November 2007 – there is no support for treating the two doses separately, and certainly no support for considering the biodistribution dose of Zevalin as a diagnostic radiopharmaceutical.

As CMS takes steps to implement section 106, CTI encourages the agency to include all doses of the Zevalin immunotherapeutic regimen within its scope. Accordingly, payment for both the biodistribution dose and the therapeutic dose would be paid based on hospital charges reduced to costs for the first six months of 2008. Because the provision only applies for the first 6 months of 2008, CTI would like to work with CMS on estimating acquisition cost for Zevalin for the third and fourth quarters of this year.

Calendar Year 2009 Payment for Zevalin

A. CMS Should Classify Zevalin as a Biologic

The reimbursement challenges for Zevalin largely stem from the decision by CMS in 2002 to pay for Zevalin as a radiopharmaceutical. As noted above, the FDA approved Zevalin under a Biologics License Application in early 2002. However, later that year, CMS classified

Zevalin as a radiopharmaceutical. In the FY 2003 hospital outpatient Final Rule published November 1, 2002, CMS concluded,

> *Because of the specific requirements associated with delivery of radioactive isotope therapy, any product containing a therapeutic radioisotope, including Y-90 Zevalin, will be considered to be in the category of benefits described under section 1861(s)(4) of the Act. Similarly, the appropriate benefit category for all diagnostic radiopharmaceuticals, including IN-111 Zevalin, is 1861(s)(3).*

Social Security Act sections 1861(s)(3) and (s)(4) do not appropriately describe the Zevalin regimen. These categories typically describe diagnostic tests and x-ray therapy. Idec Pharmaceuticals (the original manufacturer of Zevalin) filed comments with CMS on the 2004 hospital outpatient rule to challenge the classification as a radiopharmaceutical and argue that Zevalin is a biologic, but CMS did not change this determination. CMS has continued to classify Zevalin as a radiopharmaceutical.

The more appropriate benefit category for Zevalin would be 1861(2)(A) and (B) which specifically refers to "drugs and biologicals" which are not usually self-administered by patients. CMS has acknowledged that these classifications may be appropriate. On July 25, 2005, CMS concluded its National Coverage Analysis titled, "Radioimmunotherapy for Non-Hodgkin's Lymphoma" (CAG-00163N). With regard to the benefit category for Zevalin the decision memorandum states:

> *appropriate benefit categories may be found under §1861(s)(2)(A), services and supplies furnished as incident to a physician's service, and under §1861(s)(2)(B), hospital services incident to physicians' services rendered to outpatients.*

We believe the result of this determination would be a finding that the 1861(s)(2)(A) "incident to" benefit is the most appropriate classification for a biologic like Zevalin. CTI may request a National Coverage Determination of the appropriate benefit category for Zevalin.

B. CMS Should Pay Zevalin Based on ASP

CTI would like to work with CMS to establish a new payment methodology for Zevalin – that recognizes their FDA approval as a biologic. CTI believes that it would be more accurate to pay for Zevalin based on ASP, as other biologics are paid. CMS has concluded that ASP-based payment is the most accurate rate-setting methodology for other drugs and biologics, and we believe a similar conclusion is applicable to radioimmunotherapies. CTI proposes the following approach for the Zevalin regimen and does not discuss how an ASP approach may apply to the class of radiopharmaceuticals.

CMS has requested comments on how an ASP methodology may work for individual products. In the 2008 Final Rule, stated:

> *Therefore, to the extent that manufacturers or stakeholders believe that the ASP methodology that we currently use for the payment of*

separately payable drugs and biologicals under the OPPS is appropriate for their particular product, we seek comments on that approach and comments on how radiopharmaceutical ASP information could be used in future ratesetting.

Section 1847A of the Social Security Act establishes the ASP system, and notes that it applies to all "biologicals." It seems appropriate to treat products approved by the FDA under a BLA as biologicals. CTI would certify ASP based on the methodology described in section 1847A and implemented in subsequent CMS rulemaking and report Average Sales Price data for Zevalin on a quarterly basis.

CTI recognizes the unique difficulties in implementing an ASP methodology for radioimmunotherapies but CTI believes that it would be feasible for the company to collect and certify ASP. CTI would include both necessary components of the FDA-approved regimen (the biodistribution dose and the therapeutic dose) in the reported Average Sales Price. This would allow CMS to set a payment rate for both doses based on ASP. This approach would be consistent with the Social Security Act, and would better ensure patient access to these therapies.

Because Average Sales Price is a market-based methodology, we have focused on using a reporting and distribution structure that will accurately represent the actual price of the product, after taking into account all discounts and price concessions. CTI would certify an Average Sales Price based on actual direct sales of the drug to wholesalers on a quarterly basis (net of any discounts, rebates or price concessions). CTI would separately contract for the radioisotope and nuclear pharmacy compounding services that are necessary for manufacturing the final patient-specific unit dose. These costs cover necessary elements of the preparation of the patient-specific unit dose, and would not affect reported ASP, as discussed below. We believe this approach is consistent with the ASP reporting statute, and meets the goals of CMS to allow payment for biologics like Zevalin to be set based on market-based data.

The final patient-specific unit dose of Zevalin is the product of a complicated manufacturing and compounding process. In the final step of this process, a specialized nuclear pharmacy combines the monoclonal antibody Ibritumomab tiuxetan with a radioisotope that is, in many cases, provided by a different manufacturer. Due to the short half-life of these products, they are very unstable, and must be prepared shortly before they are administered. CTI has been working with the individual members of this manufacturing and distribution process to allow the company to certify a single ASP that represents the market price of the patient-specific unit dose. Additionally, at present the NDC for the Zevalin kit does not include the isotope. CTI notes that ASP is reported based on National Drug Code (NDC).

The separate contracts for the radioisotope and nuclear pharmacy compounding are necessary costs for the patient-specific preparation of Zevalin. For the purposes of ASP reporting, they would constitute a manufacturing cost or a bona fide service fee. In the 2007 Physician Fee Schedule Final Rule, CMS established the following definition for bona fide service fees:

fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on

behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

CMS went on to note that it would "interpret these elements of the definition to encompass any reasonably necessary or useful services of value to the manufacturer that are associated with the efficient distribution of drugs." The separate contracts for the necessary elements in the manufacturing and compounding process will be determined through arms-length negotiation and set at fair market value. Thus, these contracts will constitute bona fide services, and the fees will not affect the ASP reporting.

Conclusion

Developing an accurate payment methodology for Zevalin is critical to make this treatment available to patients. The stakes are high in terms of ensuring Medicare beneficiary access to these important therapies. CTI acknowledges the efforts CMS has taken to consider alternative methodologies for radiopharmaceutical payments, but we believe that a new approach is necessary to develop a payment rate for Zevalin that reflects true acquisition cost. We encourage CMS to include both doses of the Zevalin radioimmunotherapy regime under the scope of the recent legislative change to payment for radiopharmaceuticals.

CTI looks forward to working with CMS to establish an ASP methodology that would appropriately capture the market-based average sales price for the Zevalin regimen. We hope to meet with CMS in February to discuss this proposal further in order to improve the accurate reporting and payment for this product.

Thank you for your attention to this very important matter.

Respectfully submitted,

Jim Bianco, M.D.
CEO
Cell Therapeutics

Riverain MEDICAL

Practical early detection

January 25, 2008

Acting Administrator Kerry Weems
Office of the Administrator
Attention: CMS-1392-FC
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

RE: CMS-1392-FC: Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Issue Identifier: IIA4c(2) Updates Affecting OPPS Payments, Recalibration of APC Relative Weights, Changes to Packaged Services, Packaging Approach, Image Processing Services; and IIA4e Updates Affecting OPPS Payments, Recalibration of APC Relative Weights, Changes to Packaged Services Service-Specified Packaging

Dear Acting Administrator Weems:

On behalf of Riverain Medical, we would like to express our appreciation for this opportunity to submit comments regarding the Centers for Medicare and Medicaid Services' (CMS) final rule on the Hospital Outpatient Prospective Payment System (HOPPS) for Calendar Year (CY) 2008 in the OPPS Packaged Services category. Riverain Medical is a healthcare company that offers chest radiography (CXR) computer-aided detection (CAD) hardware and software for early lung cancer detection.

As you know, Riverain's CXR CAD technology is a Food and Drug Administration (FDA) premarket application (PMA) approved diagnostic tool available to help radiologists detect early stage lung cancer. CXR CAD is used by the radiologist separately from and after s/he interprets the CXR; it identifies regions of interest on CXRs that may represent nodules, which could be early stage lung cancer. CXR CAD helps to identify patients who are most likely to benefit from further work-up; potentially avoiding additional and/or more expensive tests.

Specifically, we are concerned that the final rule does not reflect the March 2007 recommendation by the Advisory Panel on Ambulatory Payment Classification Groups (Advisory Panel) to provide a separate payment for CXR CAD. We continue to agree with the Advisory Panel's recommendation and maintain that a separate payment for CXR CAD is consistent with other Medicare payment precedents. Moreover, we believe that the provision of such payment will increase access to CXR CAD, and will improve outcomes for Medicare beneficiaries, and likely prove less costly to Medicare and the nation.

Separate payment for CXR CAD will help ensure that Medicare beneficiaries and their health care providers have access to important new technology that can help detect lung cancer at its earliest stages. We respectfully draw your attention to the attached comments we submitted to the agency on January 22, 2007 and on September 14, 2007. We continue to

urge CMS to provide separate payment for CXR CAD. We thank you in advance for your attention to all of our comments and concerns.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

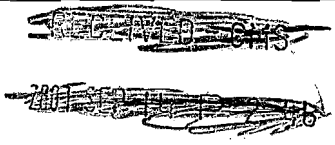
Sam D. Finkelstein
President
Riverain Medical

Enclosures: Riverain Comments to CMS January 22, 2007 and September 14, 2007

Riverain MEDICAL

Early. Detection. Now.

September 14, 2007



Acting Administrator Kerry Weems
Office of the Administrator
Attention: CMS-1392-P
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20001

Attention: CMS-1392-P

Re: CMS-1392-P; Medicare Program: Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates

Issue Identifier: OPPS: Packaged Services (II. Proposed Updates Affecting OPPS Payments, A. Proposed Recalibration of APC Relative Weights, 4. Proposed Recalibration of APC weights, e. Service-Specific Packaging Issues)

Dear Acting Administrator Weems:

On behalf of Riverain Medical, I would like to express our appreciation for this opportunity to submit comments regarding the proposed Hospital Outpatient Prospective Payment System (HOPPS) for Calendar Year (CY) 2008 in the OPPS Packaged Services category. Riverain Medical is a healthcare company that offers chest radiography (CXR) computer-aided detection (CAD) hardware and software for early lung cancer detection. Specifically, our comments will focus on the payment rate for CXR CAD - Current Procedural Terminology (CPT) codes 0174T and 0175T - in the proposed HOPPS Rule for CY 2008.

Specifically, we are concerned that the proposed rule does not reflect a recent recommendation by the Advisory Panel on Ambulatory Payment Classification Groups (Advisory Panel) to provide a separate payment for CXR CAD. We agree with the Advisory Panel's recommendation and maintain that a separate payment for CXR CAD is consistent with other Medicare payment precedents. Moreover, we believe that the provision of such payment will increase access to CXR CAD, which in turn, will improve outcomes for Medicare beneficiaries and may be less costly to Medicare and the nation.

For your reference, I am attaching previous comments we have submitted to your agency with respect to separate payment for CXR CAD. We thank you in advance for your full and fair consideration of our views and stand ready to work with you and your colleagues to ensure that Medicare beneficiaries and their health care providers have access to CXR CAD in their communities.

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Lung Cancer Early Diagnosis and CXR CAD Background

As you may know, two-thirds of lung cancer patients are 65 years or older.[1] There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.[2] Patients who have smaller primary lung tumors at diagnosis have better clinical outcomes than patients with large tumors at diagnosis. One study found that approximately two-thirds of patients with early stage lung cancer present with pulmonary symptoms[3]. The authors concluded that "a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis." As such, early detection and diagnosis of lung cancer are essential to improved survival and outcomes.

CXR is currently the most frequently used test to detect lung lesions that are suspicious for lung cancer. The American College of Chest Physicians' guidelines recommend a CXR for patients with cough and risk factors for lung cancer or metastatic cancer. Unfortunately, CXR is a poor test for detecting cancers that are less than 14 mm in size. For example, one study found that radiologists missed 71%, 28%, and 12% of lesions $\leq$ 10 mm, 10-30 mm, and 30-40 mm, respectively. The authors estimate a 23% drop in five-year survival for those patients whose lung cancers were missed.[4]

Another study indicated that survival is correlated with pathological stage (pStage) of detection. Five-year survival rates (in parentheses following the pStage) decreased as the cancer size increased and the invasive characteristics increased. Survival rates dropped from pStage IA (67%), IB (57%), IIA (55%), IIB (39%) to the largest and most invasive pStage IIIA cancers (23%)[5]. A recent study, based on the California Cancer Registry, indicates nearly five times the survival rate for those treated stage I patients, compared to those refusing treatment.[6] Therefore, a diagnostic tool that can detect lung lesions when they are small in diameter at an early pathological stage and are treatable should result in better outcomes for affected patients.

Riverain's CXR CAD technology is a Food and Drug Administration (FDA) premarket application (PMA) approved diagnostic tool available to help radiologists detect early stage lung cancer. CXR CAD is used by the radiologist separately from and after s/he interprets the chest x-ray; it identifies regions of interest on CXRs that may represent nodules, which could be early-stage lung cancer. CXR CAD helps to identify patients who are most likely to benefit from further work-up; potentially avoiding additional and/or more expensive tests. Ultimately, because CXR CAD is able to identify patients who may benefit most from chest CT, CXR CAD use may result in an increase in true positives found on chest CT scans and a

[1] Age-Specific Incidence of Lung Cancer, Environmental Protection Agency.
[2] Mery, C.M., Pappas, A.N., Burt, B.M., et al. Diameter of non-small cell lung cancer correlates with long-term survival implications for T stage. *Chest, 2005*(128), 3255-3260.
[3] Christensen ED, Harvald T, Jendresen M, et al. :The impact of delayed diagnosis of lung cancer on the stage at the time of operation. *European Journal of Cardio-thoracic Surgery* 12 (1997), 880–884.
[4] Quekel L, Kessels A, Goei R, et al. Miss rate of lung cancer on the chest radiograph in clinical practice. *Chest*, 1999(115), 720–724.
[5] Mountain, C.E., Revisions in the international system for staging lung cancer. *Chest*, 1997(111), 1710-1717.
[6] Raz DJ, Jason A. Zell JA, Ou S-HI, et al. Natural History of Stage I Non-Small Cell Lung Cancer: Implications for Early Detection. *Chest* 2007;132;193-199.

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subsequent reduction in total chest CT scans performed to follow up on suspicious CXR findings.

Data submitted by Riverain Medical to the FDA[7] in order to obtain PMA approval show that use of CXR CAD for select patients results in a significantly higher sensitivity for lung cancer detection. CXR CAD has been found to help radiologists detect more than 20% additional cancers 9-14 mm. Studies at University of Chicago[8] and University of Maryland have shown that CXR CAD identified 37% of cancers, and 38% of patients, whose cancers were *not* detected by radiologists in clinical practice. These patients could have been diagnosed earlier with CXR CAD, and likely would have had better outcomes due to earlier detection of their disease.

We are concerned about reports from physicians and hospital administrators across the country that due to insufficient reimbursement, they are not able to provide CXR CAD to the patients in their communities. We believe this poses a serious threat to access to appropriate and necessary care for Medicare beneficiaries, and we urge CMS to provide a separate payment, which will help ensure the utilization of this potentially life-saving technology. Separate payment is necessary because analysis of the Median Costs for Hospital Outpatient Services data, provided with the proposed rule, indicates that:

- reasonable usage[9] will not drive the median to allow hospitals to recover their investment for the technology;
- a hospital can only expect to earn $2.36 per CXR in CY 2008, which is not enough to support the use of this important technology; and
- a hospital can expect to lose $0.49 on every procedure in APC0260, which prohibits a hospital from absorbing the cost of CXR CAD.

[7] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.
[8] Li F, Engelmann R, Metz C, et al. Results Obtained by a Commercial Computer-aided Detection (CAD) Program with Radiologist Missed Lung Cancers on Chest Radiograph. *Radiology*, in Press, 2007.
[9] Riverain Medical expects the usage of CXR CAD to be less than 50% even if all appropriate chest x-rays were read with computer-aided detection for the following non-exhaustive reasons:

a. Portable chest x-rays are not suitable for CXR CAD,
b. Not all Medicare recipients are age-appropriate (some are too young, others are too old),
c. Some recipients are not eligible for surgical treatment, and/or
d. Not all recipients have symptoms or risk factors suggesting CXR CAD is reasonable.

The following table shows the increase in median as the percentage use of CXR increases:

CXR CAD Usage (%)	Reimbursement ($)	Increase in median ($)
0	46.23	0.00
10	46.72	0.49
20	46.72	0.49
50	47.08	0.85

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Riverain Urges CMS to Adopt Advisory Panel Recommendation

As noted above, on March 8, 2007, the CMS Advisory Panel voted affirmatively to recommend to CMS that it assign a "special" packaged code ("Q" status) to 0175T and provide a separate payment for CY 2008. We are concerned that in the proposed HOPPS rule, your agency has not adopted this recommendation. We urge you to include, in the final CY 2008 rule, this recommendation and also to extend it to 0174T. Specifically, we respectfully request that a separate payment of $15 be made for each use of CXR CAD, just as currently is the case with separate Medicare payment for mammography CAD.

We feel strongly that Medicare payment policies should not create barriers to access to much-needed technology for beneficiaries. Given that this new technology represents an additional cost to the hospital, above and beyond the cost of other radiology supplies and equipment, a payment rate of $15 will enable hospitals to be reimbursed for the cost of purchasing and using CXR CAD and help ensure beneficiary access to the technology.

Summary

We believe that the assignment of status indicator "Q" with separate payment of $15 for CPT codes 0174T and 0175T would help to create efficient and cost-effective delivery of this reasonable and necessary technology, which provides essential information to the treating physician to appropriately guide the further diagnosis, treatment, and management of a patient's lung cancer. Additional payment for CXR CAD will help ensure that Medicare beneficiaries and their health care providers have access to important new technology that can help detect lung cancer at its earliest stages. At $15, we feel the cost-effectiveness for CMS of CRX CAD use is very high; by helping to find solitary pulmonary nodules, the use of CXR CAD may reduce the utilization of more expensive technologies – diminishing patient exposure to radiation and reducing the stress and cost associated with another test. We believe that the utilization of CXR CAD will help preserve scarce health care resources and save lives.

We appreciate the opportunity to submit these comments. My staff and I would be happy to answer any questions you may have. I can be reached at 800.990.3387 or via mobile phone at 330.284.3264. Thank you again for your consideration of the provision of a separate payment for CXR CAD.

Sincerely,

Sam D. Finkelstein

Sam D. Finkelstein
President

Enclosure: January 22, 2007 Comment Letter

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January 22, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1506-FC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: File Code CMS-1506-FC; Medicare Program; The Hospital Outpatient Prospective Payment System and CY 2007 Payment Rates - Final Rule

Dear Center for Medicare and Medicaid Services:

Riverain Medical appreciates the opportunity to submit these comments regarding the Outpatient Prospective Payment System (OPPS) Final Rule for Calendar Year (CY) 2007. Riverain Medical is a healthcare company that offers chest radiography (CXR) computer-aided detection (CAD) hardware and software for early lung cancer detection, which is PMA approved by the FDA. Riverain Medical is committed to being a leader and innovator in CAD and diagnostic technologies that significantly aid medical practitioners in the early-stage detection of diseases.

Riverain Medical is commenting on the proposed payment of CXR CAD in the final OPPS Rule for CY 2007. Under the final rule CXR CAD, described by Category III Current Procedural Terminology (CPT) codes 0174T and 0175T, will not receive a separate APC payment in CY 2007 because of CMS' decision to assign it a status indicator of "N." CMS also decided to bundle payment for CXR CAD into payment for APC 0260, Level I Plain Film Except Teeth.

Riverain Medical disagrees with CMS' decision to assign CXR CAD a status indicator of "N" and bundle it into payment for APC 0260 for CY 2007. CXR CAD should be assigned to APC 1492 with a status indicator of "S".

Background

For your convenience, the CPT codes are provided on the AMA web site (http://www.ama-assn.org/ama1/pub/upload/mm/362/07catiiicodes121506.pdf are:

> 0174T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed concurrent with primary interpretation, and
>
> 0175T Computer aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s), performed remote from primary interpretation.

Extensive data on the ability of CXR CAD to detect lung cancers from numerous studies was presented to the Advisory Panel on Ambulatory Payment Classification Groups (Advisory Panel). Having heard the evidence, the Advisory Panel voted that 0175T should be packaged

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with additional payment using a status indicator of "Q". However, the final minutes of the meeting indicate that the Advisory Panel's final recommendation was not to provide additional payment, and CMS accepted this final recommendation.

While we accept that the Advisory Panel recommended CMS assign status indicators of "N" to 0174T and 0175T for CY 2007, we respectfully disagree with their final recommendation and ask that CMS assign status indicators of "S" and place them in New Technology APC 1492 with a payment rate of $15. We maintain that a modest new technology payment under APC is consistent with payment precedents, will improve outcomes for Medicare beneficiaries, and may be less costly.

Summary of supporting rationale

We understand that this letter is long because of all the reasons that support our request for reassignment. Consequently, we summarize the key reasons to change CMS' decision below. Each point is addressed at length after the summary. The numbers match the section where the reason is addressed.

1. Third-party payers paid $27.00 for use of CXR CAD
   - Private payer payment of $27 is consistent with Medicare payment of $15.
2. The original vote by the APC panel on August 23, 2006 was to assign a "special" packaged code ("Q" status) to 0175T
   - "Remote" can be a different time, place, or physician.
   - Providers may not have "arrangements" for reimbursement for CXR CAD.
3. CXR CAD will *not* be reimbursed when bundled with chest x-ray by driving the median cost higher
   - The median will be increased only by $2.00 with 50% utilization of CXR CAD.
   - Riverain Medical is not promoting over-utilization of CXR CAD but CMS's decision may cause over-utilization in order to obtain reimbursement.
4. Continuous product improvement lowers false positives
   - Lower false positives should reduce the call back rate.
5. CT, MRI, and PET are expensive ways to detect lung cancer
   - CT, MRI, and PET could be used routinely when CXR CAD is not available.
   - CT, MRI, and PET will likely be used only when the radiologist using CAD suspects lung cancer.
   - CT, MRI, and PET payment for 2007 are $298, $349, and $855, respectively, based on the final rule.
   - The cost of CT screening is estimated to be $115 billion. The estimated cost of paying for the use of CXR CAD, which is not screening, is $250 million over 5 years and $1 billion over 10 years.
   - CT subjects patients to large amounts of radiation. CXR CAD does not add any radiation because it uses existing chest x-rays taken for medical reasons.
   - More lung cancers are detected from chest x-rays than from chest CT.

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- CXR CAD was proven to help radiologists detect more than 20% additional cancers 9-14 mm.

6. CXR CAD is a diagnostic tool, not a screening test
   - There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.
   - Riverain Medical's CXR CAD was developed and was shown, to help radiologists detect early stage lung cancer.
   - Studies show that CXR CAD identified 37% of cancers, and 38% of patients, whose cancers were *not* detected by radiologists in clinical practice. These results were reported by researchers at the University of Chicago and University of Maryland. These patients could have been diagnosed earlier with CXR CAD.
   - One study showed that approximately two-thirds of patients with early stage lung cancer present with pulmonary symptoms. The authors concluded that "a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis."
   - The American College of Chest Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer.
   - CXR CAD is a diagnostic tool that identifies patients who are most likely to benefit from further work-up; potentially avoiding a more expensive workup.
   - Therefore, CXR CAD should improve the early detection of lung cancer and the clinical outcomes for such patients.
   - CXR CAD is used by the radiologist separately from and after s/he interprets the chest x-ray.
   - CMS could establish reasonable coverage restrictions to limit the use of the technology, instead of not paying for its proper use.
   - The cost-effectiveness is very high for a $15 payment for CXR compared to using CT, MRI, or PET before further workup is indicated.
7. Use of CXR CAD *acts* like a prevalence screen and will therefore find lung cancers
   - Prevalence screens detect more lung cancers than incidence screens.
   - Chest x-rays are typically taken on different patients each year.
   - Therefore, use of CXR CAD is likely to be a highly effective and highly cost-effective way of detecting lung cancers in early stages in patients who are symptomatic *without screening*.
8. CXR CAD should *not* be bundled into the APC Payment for chest x-ray (APC 0260).
   - CMS policy is to bundle payments for two procedures when the resources used to provide those procedures cannot be distinguished.
   - If the median of APC 0260 drives reimbursement, then hospitals that use CXR CAD are penalized; those who do *not* are rewarded. Users need to buy separate equipment and thus have expenses related to its use.
   - $15 is 34.4% of $43.60, the payment for APC 0260 in 2007. This percentage is too high for hospitals to absorb.

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- Other radiologic procedures that are similar to CXR CAD are paid separately:
  - Three dimensional post-image processing,
  - Mammography CAD, and
  - Radiology guidance procedures.
- By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries.
- CXR CAD should be paid separately under OPPS as a matter of policy consistency.
- CXR CAD should be paid separately under OPPS as a matter of fairness.
- CXR CAD should be paid separately under OPPS to allow access to Medicare beneficiaries.

9. APC Assignment for CXR CAD

- CXR CAD is a new technology, has a CPT Category III code and should be assigned to new technology APC 1492, with a category "S" status indicator.

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Supporting Rationale

1. Third-party payers paid $27.00 for use of CXR CAD

Third-party payers paid $27 for the use of CXR CAD (via CPT code 0152T in CY2006)[1]. The payers represent approximately 60 million covered lives. Payment of $27 by third-party payers is consistent with a payment of $15 by Medicare.

2. The original vote by the APC Advisory Panel on August 23, 2006 was to assign a "special" packaged code ("Q" status) to 0175T

Riverain Medical is not certain how and why this APC Advisory Panel vote was overturned. However, based on the comments with the final rule, "They questioned the meaning of the word "remote" in the code descriptor for CPT code 0175T, noting that is was unclear as to whether "remote" referred to time, geography, or a specific provider. They thought it was likely that a hospital without a CAD system that performed a chest x-ray and sent the x-ray to another hospital for performance of the CAD would be providing the CAD service under arrangement and, therefore, would be providing at least one other service (chest x-ray) that would be separately paid." While all three conjectures are accurate, it is important to note that providers of CAD do not necessarily have "arrangements" to read CAD. The attached letter indicates that "arrangements" may not exist and reimbursement for the CAD reading is necessary to provide the service.

3. CXR CAD will not be reimbursed when bundled with chest x-ray by driving the median cost higher

We disagree with CMS's supposition, "To the extent that CAD may be more frequently provided in the future to aid in the review of diagnostic chest x-rays as its clinical indications evolve, we expect that its cost would also be increasingly reflected in the median costs for chest x-ray procedures." Chest x-rays make up 51% of the utilization of APC 0260. Consequently, even with 50% utilization of CXR CAD, only 25.5% of the APC class is affected. Using CMS data provided with the preliminary rule and a $15 payment amount the actual reimbursement changes according to the chart and numbers below, based on a simulation. In particular, note that with a 50% utilization of CAD on existing chest x-rays the hospital can expect to receive only $2; $1 for the CXR CAD and $1 for the 49% of other procedures in the APC. $9 is paid when 75% of chest x-rays are read with CAD. $14 is paid for 95% utilization. Riverain Medical is neither promoting over-utilization of CXR CAD nor screening; CXR CAD is not expected to have high enough utilization to materially affect the median. CMS policy of not providing separate payment may promote over-utilization in order to obtain reimbursement.

[1] *Aunt Minnie* October 24, 2006. Aunt Minnie is the largest and most comprehensive community Web site for medical imaging professionals worldwide.

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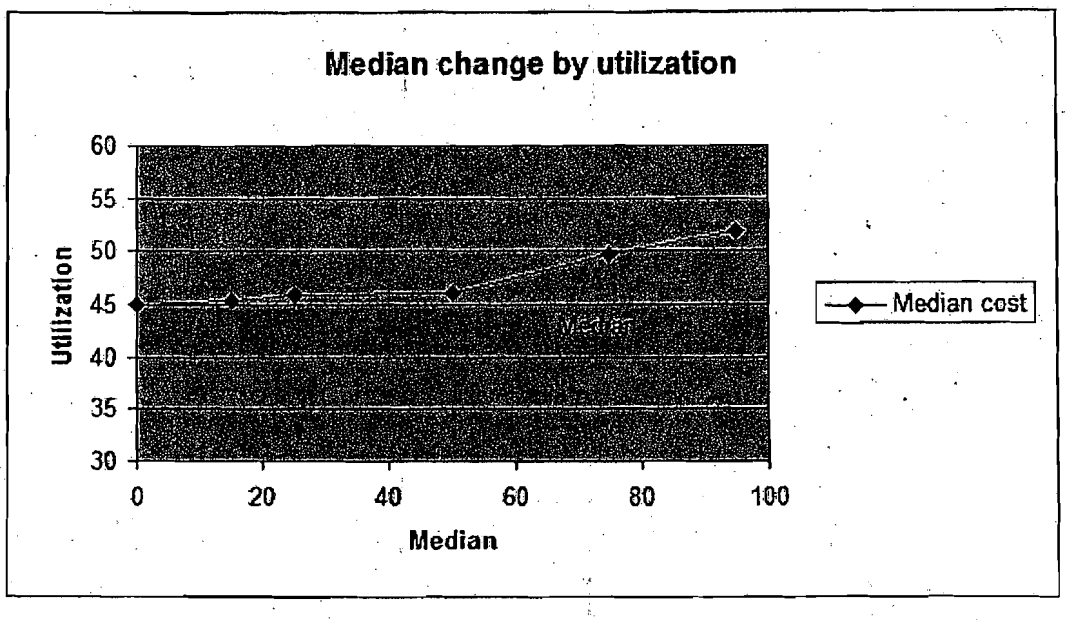

Hospital Analysis; Every procedure in APC 0260 is paid more when median increases

Example 1: 95% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$7	chest x-ray
Other APC 0260	49	$7	Other APC 0260
		$14	Total to hospital

Example 2: 75% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$5	chest x-ray
Other APC 0260	49	$5	Other APC 0260
		$9	Total to hospital

Example 3: 50% utilization of CAD

	% Utilization*	Additional Revenue	
Chest x-ray	51	$1	chest x-ray
Other APC 0260	49	$1	Other APC 0260
		$2	Total to hospital

* Note that % utilization refers to % of the APC group. The utilization of chest x-ray remains at 51% because Riverain Medical is *not* advocating screening. The examples given here change the usage of CXR CAD on the constant number of chest x-rays.

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4. Continuous product improvement lowers false positives

On November 1, 2006 FDA approved Riverain Medical's PMA supplement for the newest version of its CXR CAD, which lowers the false positive rate by 30%. This achievement should translate into fewer call backs for further work up.

5. CT, MRI, and PET are expensive ways to detect lung cancer

The results of a large collaborative study conducted by the International Early Lung Cancer Action Program (I-ELCAP) investigators were reported in the October 26, 2006 New England Journal of Medicine[2]. The investigators concluded, "We found CT screening for lung cancer to be highly cost-effective". However a study published in JAMA in 2003[3] indicated that "The total societal cost for an annual helical CT screening program of at-risk ever-smokers is very high. An estimated 50 million men and women in the United States are ever-smokers between the ages of 45 and 75 years. If 50% of this group received periodic annual screening, the program costs are approximately $115 billion (discounted) based on our study estimates." Compare that to the Congressional Budget Office's (CBO) estimate of the cost of CXR CAD, $250 million over 5 years and $1 billion over 10 years[4].

Another cost besides the dollar cost of finding lung cancer with CT screening is the radiation cost. Radiation causes cancer. CXR CAD does not add any radiation to that of the chest x-ray.

CXR CAD used on existing chest x-rays is a cost-effective alternative. More lung cancers were found on routine chest x-rays (101) than CT scan (32) in a retrospective chart review covering more than 5 years of lung cancer patients referred to the Weill-Cornell Medical College thoracic surgery service with biopsy proven non-small-cell lung cancer (NSCLC) who were asymptomatic at presentation[5]. Weill-Cornell Medical College is one of the ELCAP centers. The actuarial 5-year survival in the CXR group was 84% of stage IA, 55% for stage IB and 28% for all other stages combined. Unfortunately, only 39% of cancers in stage IA were found on chest x-rays. More lung cancers could have been found with CXR CAD because CXR CAD was proven to help radiologists detect more than 20% additional 9-15 mm lung cancers.[6] It makes more sense to allow CXR CAD to be used on chest x-rays than to subject patients to CT because CXR CAD costs less in dollars and in radiation exposure to patients. CMS can help the fight against lung cancer by providing a separate reimbursement for CXR CAD.

The cost for a CRX CAD image is too high for a hospital to absorb under the $43 payment obtained for an X-ray. Hospitals without CRX CAD are more likely to refer patients internally to a spiral CT, MRI, or PET scan if the diagnosis is uncertain. The payment for a CT (HCPCS 71275), MRI (HCPCS 71550), or PET (HCPCS 78811) are $298, $349, and $855, respectively. Contrast that with the situation that the physician chooses a CXR CAD image. S/he would

[2] The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006;355:1763-71.
[3] Mahadevia PJ, Fleisher LA, Frick KD, et al. Lung cancer screening with helical computed tomography in older adult smokers; A decision and cost-effectiveness analysis. *JAMA* 2003;289:313-322.
[4] Analysis by Congressional Budget Office November 2006.
[5] Altorki N, Kent M, and Pasmantier M. Detection of early-stage lung cancer: computed tomographic scan or chest radiograph? *J Thorac Cardiovasc Surg* 2001;121:1053-7.
[6] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

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simply refer the x-ray to a center that has that technology and let that center file for reimbursement.

6. CXR CAD is a diagnostic tool, not a screening test

There is accumulating clinical evidence that clinical outcomes from lung cancer are directly related to primary tumor size at diagnosis.[7] Patients who have smaller primary lung tumors at diagnosis have better clinical outcomes than patients with large tumors at diagnosis. CXR is currently the most frequently used test to detect lung lesions that are suspicious for lung cancer. Unfortunately, CXR is a poor test for detecting cancers that are less than 14 mm in size. For example, one study found that radiologists missed 71%, 28%, and 12% of lesions $\leq$ 10 mm, 10-30 mm, and 30-40 mm, respectively. The authors estimate a 23% drop in five-year survival for those patients whose lung cancers were missed.[8] Another study indicated that survival is correlated with pathological stage (pStage) of detection where pStages IA, IB, IIA, IIB, and IIIA were associated with 67%, 57%, 55%, 39%, and 23%, respectively[9]. Therefore, a diagnostic tool that can detect lung lesions when they are small in diameter and in an early pathological stage should result in earlier detection and treatment of lung cancer. Riverain's technology for CXR CAD is a PMA approved diagnostic tool available for this purpose. Moreover, recent evidence has shown that early detection and treatment of lung cancer with chemotherapy is correlated with prolonged five-year survival rates.[10] The I-ELCAP investigators reported a 92% 10-year actuarial survival rate of patients with clinical stage I cancer who underwent surgical resection within 1 month after diagnosis[11]. The body of evidence indicates that CXR CAD should improve clinical outcomes for these patients.
CXR CAD identifies regions of interest on CXRs that may represent nodules, which could be early-stage lung cancer. It employs a multi-step image enhancement and analysis processing system that consists of a series of algorithms and classification technologies to identify regions that may contain indications of cancer and isolating them from the normal structure of the heart, blood vessels, ribs and other structures of the chest. The system includes digital image processing for noise reduction, image enhancement, anatomy segmentation, feature extraction, pattern recognition, neural network computing, and fuzzy logic.

A recent study conducted at the University of Chicago indicated that 37% of missed lung cancers could have been detected earlier if CXR CAD was used. Similarly, a recent study at the University of Maryland demonstrated that 38% of the patients with missed lung cancer could have been detected earlier if the x-rays were interpreted with CXR CAD.

One study showed that approximately 2/3 patients with early stage lung cancer present with pulmonary symptoms[12]. The authors concluded that, "...a delay of even 3-4 months might be fatal and send the patient into a stage with a poor prognosis." The American College of Chest

[7] Mery, C.M., Pappas, A.N., Burt, B.M., et al. Diameter of non-small cell lung cancer correlates with long-term survival implications for T stage. *Chest*, *2005*(128), 3255-3260.
[8] Quekel L, Kessels A, Goei R, et al. Miss rate of lung cancer on the chest radiograph in clinical practice. *Chest*, 1999(115), 720-724.
[9] Mountain, C.E., Revisions in the international system for staging lung cancer. *Chest*, 1997(111), 1710-1717.
[10] Winton, T., Livingston, R., Johnson, D., et al. Vinorelbine plus cisplatin vs. observation in resected non-small-cell lung cancer. *N Engl J Med*, *2005*(352), 2589-2597.
[11] The International Early Lung Cancer Action Program Investigators. Survival of Patients with Stage I Lung Cancer Detected on CT Screening. *N Engl J Med* 2006;355:1763-71.
[12] Christensen ED, Harvald T, Jendresen M, et al. :The impact of delayed diagnosis of lung cancer on the stage at the time of operation *European Journal of Cardio-thoracic Surgery* 12 (1997), 880-884.

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Physicians' guidelines recommend a chest x-ray for patients with cough and risk factors for lung cancer or metastatic cancer[13]. Such patients with suspicious chest x-rays could benefit from CXR CAD.

CXR CAD is not a chest x-ray and is not a screening test. CXR CAD is not a screening test; it is a diagnostic tool that identifies symptomatic patients who are most likely to benefit from additional workup.

CXR CAD is performed separately from, and after, a CXR when there is a finding from the patient's history and physical (e.g., a smoker with bloody sputum) that indicates a high risk of lung cancer and/or the radiologist continues to be suspicious of lung cancer after interpreting the CXR. CXR CAD results in the production of new images, which must be read by a radiologist, in addition to the initial CXR images. Typically, the radiologist will review the CXR CAD images side-by-side with the CXR images in order to determine whether a lesion requires further work-up. CXR CAD independently identifies suspicious and/or subtle nodules the radiologist may have not seen on the CXR.

Data submitted by Riverain Medical to the FDA[14] in order to obtain PMA (premarket approval) shows that use of CXR CAD for select patients results in a significantly higher sensitivity for lung cancer detection. Ultimately, because CXR CAD is able to identify patients who may benefit most from chest CT, CXR CAD use may result in an increase in true positives found on chest CT scans and a significant reduction in total chest CT scans performed to follow up on suspicious CXR findings.

There is no basis for believing that CAD will increase the number of CXRs performed in the outpatient or office setting because CXR CAD is not a screening tool and is not applied "automatically" to screening CXRs. It should be applied only to CXRs suspicious for lung cancer on the basis of a high prior probability of lung cancer based on a patient's history or physical examination. Using CXR CAD for screening is not its proper use.

CMS is justifiably concerned about the impact of costs of new technology on the Medicare Trust Fund. We often heard behind the scenes that CMS is concerned that every lung X-ray will receive CRX CAD. We disagree. As an alternative to effectively making the technology non-covered for all indications through payment policy, CMS could establish reasonable payment and then have appropriate coverage restrictions to prevent inappropriate overuse of this technology. CMS may wish to consider the savings from avoiding substantially more expensive imaging modalities. At $15, the cost-*effectiveness* of CRX CAD is very high. Contrast that cost with the cost of CT, MRI, or PET.

Riverain Medical understands that Medicare does not pay for screening. Comparisons made in sections *§5. CT, MRI, and PET are expensive ways to detect lung cancer* (above) and *§7. Use of CXR CAD acts like a prevalence screen and will therefore find lung cancers* (below) should not be misconstrued to think that CXR CAD is screening. These comparisons are made to show that CXR CAD can be a cost-effective alternative to CT screening. Expected results would be that many lung cancers could be detected early at a fraction of the costs. Annual screening

[13] Kvale, P.A. Chronic cough due to lung tumors: ACCP evidence-based clinical practice guidelines. *Chest, 129*(1), 147S-153S, January 2006 Supplement.
[14] Summary of Safety and Effectiveness Data for RS-2000, PMA #P000041, Approved July 12, 2001.

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with CT would find more lung cancers but at a much higher price, as discussed in §5. *CT, MRI, and PET are expensive ways to detect lung cancer.*

7. Use of CXR CAD acts like a prevalence screen and will therefore find lung cancers

The I-ELCAP study discussed above found 348 (84%) lung cancers on baseline (prevalence) screening. Only 64 (16%) lung cancers were found on annual (incidence) screenings. The use of CXR CAD on existing chest x-rays will be similar to prevalence screening because typically new (different) patients are x-rayed each year, not the same patient x-rayed at designated intervals. CXR CAD may be an effective alternative to instituting a costly CT screening program.

8. CXR CAD should not be bundled into the APC Payment for CXR

It is inappropriate to bundle payment for CXR CAD into the payment for CXR, APC 0260.
CMS policy is to bundle the costs of two procedures when the resources used to provide those procedures cannot be distinguished. For example, the vast majority of radiology related procedures with status indicator "N" are "injection" procedures (e.g., injection of contrast into a blood vessel) where the hospital also bills for the actual x-ray as well. It is extremely difficult, if not impossible, for the hospital or CMS to distinguish between the cost of the "injection" and the cost of the x-ray itself.

Bundling APC 0260 does not and is not likely to ever cover costs of CXR CAD. For those who use CXR CAD, cost is never recovered because it applies to only one procedure in the APC (CXR) and to a vast minority of those procedures. Costs will always be incompletely reflected in APC payment. A user of CXR CAD always ends up with incomplete reimbursement for expense of providing CXR CAD. In effect, those hospitals that do *not* use CXR CAD are rewarded while those that use CXR CAD are penalized. As discussed in §3. *CXR CAD will not be reimbursed when bundled with chest x-ray by driving the median cost higher.* An analysis of the utilization data that CMS provided with the proposed rule indicates that the median is not likely to be impacted unless CXR CAD is used in a very high percentage of chest x-rays. Riverain Medical does not expect that utilization of CXR CAD, if it is assigned a status indicator of "N," will ever be high enough to appropriately and adequately change the median cost of procedures in APC 0260.

Please note that $15.00, the requested payment amount, is 34.4% of $43.60, the payment for APC 0260 in 2007. 34.4% is a very high percentage of total payment. It is much higher than is typically associated with bundled procedures. In fact, CMS recognizes that low-cost new technologies should be paid separately because it established new technology APC's for that very purpose. Note also that $15.00 is consistent with payments by third-party payers, as discussed in §1. *Third-party payers paid $27.00 for use of CXR CAD.* The cost for a CRX CAD image is too high to absorb under the $43 payment obtained for an X-ray. Hospitals without CRX CAD are more likely to refer patients internally to a spiral CT, MRI, or PET scan if the diagnosis is uncertain. However, if the physician prefers a CXR CAD analysis, they would simply refer the x-ray to a center that has CXR CAD technology and let that center file for reimbursement.

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Separate resources are necessary for CXR CAD. The resources, including the staff and equipment needed to deliver CXR CAD, are completely different, and distinguishable from those required to perform a CXR. Specifically, CXR CAD requires special software, hardware, information systems, and information technology staff whereas taking a CXR requires an x-ray machine, a radiology technician, and software that is entirely different from CXR CAD software.

Furthermore, CXR CAD is not only performed separately from a CXR, but is performed, not infrequently, at a different time and/or location and/or by a different radiologist from the CXR ("remote"). Typically this happens when a CXR is obtained in the emergency department at one time with the interpretation performed (by a radiologist) at another time. The interpretation would include a recommendation that CAD be applied to the images. Subsequently, after discussion with the treating physician, CAD is ordered and applied to the original CXR images on a different day. In this situation it is appropriate for the hospital to bill separately for CAD because it is an entirely different procedure performed on an entirely different day from the CXR. This example illustrates that the resources required for CXR CAD are entirely different from the resources required for CXR and thus it is inappropriate to bundle payment for CXR CAD into payment for CXR.

The FDA recognized that CAD would be performed after reading the chest x-ray. The labeling for the device states, "The device is intended for use as an aid only after the physician has performed an initial interpretation of the radiograph."

The American Medical Association (AMA) recognizes that CXR can be read remote from the chest x-ray and created CPT Code 0175T for that use.

Below are several examples of radiologic procedures that are similar to CAD yet paid separately:

- Three-dimensional post-image processing - CMS, in the OPPS final rule for CY 2006, announced it would make separate payment for CPT codes 76376 and 76377, "3D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image post-processing on an independent workstation" (76376), and "requiring image post-processing on an independent workstation" (76377). These codes are used to report the use of image post-processing technologies similar to CXR CAD and, just like CXR CAD, the resources (e.g., the software, hardware, and staff time needed to apply computer algorithms to radiologic images) used to generate these new images are entirely different, and distinguishable from, the resources used to generate the original images (e.g., the CT scan). These technologies, like CXR CAD, generate new images that must be interpreted in addition to (i.e., side-by-side with) the original radiologic (or MRI) images. CMS assigned CPT codes 76376 and 76377 to APC category 0340 and 0282 with a payment rate of $37.51 and $37.81, respectively, for CY2007.

- Mammography CAD - Mammography CAD, CPT code 76082, Computer-aided detection (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation, with or without digitization of film radiographic images; diagnostic mammography, is paid separately under OPPS. Because separate payment, at the same rate as under the Medicare Physician Fee Schedule (MPFS), is required by statute, the same policy should be applied to CXR CAD.

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- Radiology "guidance" procedures - CMS makes separate payment for radiology "guidance" procedures. These are procedures where radiology equipment such as a CT scanner is used at the time of a surgical procedure to help "guide" the surgeon to improve the outcome or reduce the risk of a procedure such as a tumor removal or biopsy. This policy exists because CMS recognizes that the resources used to provide "guidance" are different and distinguishable from the resources used to perform the surgical procedure.

By not making separate payment for CXR CAD, CMS has made it more likely that hospitals will not make CXR CAD available to Medicare beneficiaries. CXR CAD represents an additional and non-reimbursable cost to the hospital above and beyond the cost of a CXR. If hospitals, especially rural and smaller community hospitals, are not paid separately for CXR CAD, they may be less likely to invest in this technology, thereby denying beneficiary access to CXR CAD. In addition, mammography CAD and three dimensional post-processing imaging are paid separately, creating an incentive for hospitals to provide those technologies but not CXR CAD. This is unfair and does not permit the marketplace to assess the true value of CXR CAD as it does for the other comparable technologies. Bundling creates an unfair playing field and does not allow the marketplace and the medical community to determine the value of CAD and make a judgment as to its relative costs and benefits. CMS should not substitute its own value judgment for that of the marketplace. More importantly, however, not having CXR CAD available may limit the quality of care afforded to patients who may have lung cancer. Please note that two-thirds of lung cancer patients are diagnosed at age 65 years old or older. Denying beneficiary access to CXR CAD is effectively delaying their chance of early detection and treatment (i.e., reducing their chance of surviving lung cancer).

CXR CAD should be paid separately under OPPS both as a matter of policy consistency and as a matter of fairness. Separate payment for post-processing technologies is consistent with current CMS policy and bundling is a deviation from that policy. CXR CAD is a new technology with its own Category III CPT codes and OPPS policy is to assign a payment amount to Category III CPT codes irrespective of their costs or clinical benefits.

9. APC Assignment for CXR CAD

A Payment of $15 should be made for CXR CAD. This technology represents a significant additional cost to the hospital above and beyond the cost of other radiology supplies and equipment. We propose that CXR CAD be placed in APC 1492 with status indicator "S", with a payment rate of $15. A payment rate of $15 will enable hospitals to be reimbursed for the cost of purchasing and using CXR CAD. Alternatively, we propose assigning a status indicator of "Q" to 0174T and 0175T in CY 2007 with a separate payment of $15. We would like to point out that in August 2006 the Advisory Panel on Ambulatory Payment Classification Groups initially voted to recommend a "Q" status for 0175T with additional payment for its use.

Conclusion

CXR CAD identifies regions of interest on CXRs that are suspected nodule sites, an important indicator of early lung cancer. For CY 2007, CMS gave CXR CAD a status indicator of "N" and bundled it into payment for APC 0260. Resources used to deliver CXR CAD are completely different from those required to perform a CXR. Riverain Medical disagrees with the Advisory

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Panel on Ambulatory Payment Classification Groups' final recommendation to assign CXR CAD technology a status indicator of "N" and bundle it into payment for APC 0260. We request, as a matter of policy consistency, fairness, and Medicare beneficiary access, that CMS make a separate payment for CXR CAD and change the status indicator of CPT code 0174T and 0175T in CY 2007 to "S" and assign it to APC 1492 with a payment rate of $15.

We appreciate the opportunity to submit these comments on the Proposed Rule CMS-1506-FC and would be happy to answer any questions you may have. I may be contacted at 800.990.3387 or my mobile phone at 330.284.3264.

Thank you for your consideration of separate payment for chest x-ray computer-aided detection.

Sincerely,

RIVERAIN MEDICAL

Sam D. Finkelstein

Sam D. Finkelstein
President
Riverain Medical

Attachment: Letter from Rocky Pahwa, CEO AZ-Tech Radiology & Open MRI

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AZ-TECH RADIOLOGY & OPEN MRI
Open MRI, MRA Ultrasound, CT, X-Ray, Bone Density, & Mammography

Date: December 18, 2006

To: Riverain Medical
3020 South Tech Boulevard
Miamisburg, OH 45342

Dear Riverain Medical,

I am willing to ask for coding and reimbursement guidance. My radiology group practices in a rural area of Arizona. None of the hospitals or physicians offices in our area offer computer aided detection (CAD) for chest x-rays. As you know, we offer CAD in our practice and we plan to offer CAD to the hospitals and physicians in our area who do not provide it.

These other providers will send us film or digital chest radiographs after they determine that CAD is medically necessary. Because the other providers do not want to enter into a business arrangement with us, we will bill Medicare and other payers for CAD while the other providers will bill for the chest film. The current CPT code for CAD is an add-on code, which means we will be unable to use it because we are not billing for interpreting the chest film. Please advise us on how we can bill for CAD under these circumstances. If we cannot be reimbursed for CAD then we will not be able to provide it.

Thanks,

Rocky Pahwa
CEO