



January 3, 2011

Donald Berwick, MD, MPP, FRCP
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1504-FC
P.O. Box 8013
Baltimore, MD 21244-1850

Re: CMS 1504-FC, Medicare Program: Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates and Ambulatory Surgical Center Payment System and CY 2011 Payment Rates

Dear Dr. Berwick:

On behalf of the American College of Gastroenterology (ACG), the American Gastroenterological Association (AGA), the American Society for Gastrointestinal Endoscopy (ASGE) and our 18,000 physician members specializing in digestive diseases, we are pleased to comment on CMS's final rule with comment period, CMS-1504-FC, published on Nov. 24, 2010 in the *Federal Register*, regarding changes to the hospital outpatient prospective payment system (HOPPS) and ambulatory surgical center (ASC) payment system for CY 2011.

Our comments focus on the following four issues:

- Waiver of coinsurance for services furnished in connection with a colorectal cancer screening test that becomes diagnostic or therapeutic
- Upper GI CPT code reassignment within the APC system (APC 0141/0422)
 - Our initial comments to CMS's proposed rule which suggested a three-tiered APC system for the upper GI codes
 - In response to the final rule, a proposal to move CPT code 43228 from APC 0422 to APC 0384 in order to mitigate access to care issues for beneficiaries
- Assigning the Smart Pill GI monitoring system for gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule (HCPCS code 0242T) to an APC
- Method of updating ASCs

Waiver of Coinsurance for Services Furnished in Connection with a Colorectal Cancer Screening Test that Becomes Diagnostic or Therapeutic

Sec. 4104 of the Affordable Care Act (ACA) requires that effective Jan. 1, 2011, the deductible for colorectal cancer screenings be waived for Medicare patients regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.

Sec. 4104 waives the beneficiary coinsurance for covered preventive services that have a grade “A” or “B” from the U.S. Preventive Services Task Force (USPSTF). Colorectal cancer screening by colonoscopy or flexible sigmoidoscopy, which have a grade “A” from the USPSTF, are unique preventive services because when pre-cancerous polyps are detected they are removed at the same time, thus preventing colorectal cancer as opposed to detecting cancer at an early stage. **We believe that CMS should seek authority under Sec. 4104 of the ACA to waive coinsurance for a colorectal cancer screening regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as a screening test.**

At a minimum, we believe that CMS should reduce the financial burden on Medicare beneficiaries by waiving the coinsurance requirement for the increment of the procedure that is screening in nature. As a result, coinsurance would only apply to the diagnostic test and to other services furnished in connection with, as a result of, and in the same clinical encounter as the screening test. We note that if a screening colonoscopy was performed and a polyp was found and removed by snare cautery, this would be billed as CPT code 45385. In fairness, the coinsurance should be applied only to the amount of the fee schedule difference between code 45385 minus the colorectal cancer screening codes G0121/G0105.

Upper GI CPT code reassignment within the APC system (APC 0141/0422)

We are disappointed that CMS finalized its proposal to reassign CPT codes 43242, 43216, 43510, and 43870 from APC 0141 to APC 0422. We think CMS’s decisions regarding the assignment of CPT codes to these APCs are internally inconsistent and incorrect.

CMS decided that it was “necessary” to reassign CPT code 43242 to a higher paying APC because the median cost for the code was “significantly higher” than the median cost for APC 0141 (75 FR 71907). The difference between the proposed rule median cost of CPT code 43242 (\$1,074) and the proposed rule median cost of APC 0141 (\$608) is \$466. On the other hand, CMS determined that it was appropriate to keep CPT code 43228 in APC 0422, even though the difference between the final rule median cost for CPT code 43228 (\$1,797) and the final rule median cost of APC 0422 (\$1,137) is \$660, because the median costs were “relatively similar.”

It is not clear how a median cost difference of \$466 can be interpreted as sufficient to warrant the reassignment of one CPT code to a different APC, when a greater median cost difference was termed to be “relatively similar” and thus not warranting the assignment of the code to a different APC. CMS’s decision to move CPT codes 43242, 43216, 43510 and 43870 into APC 0422 has changed the value of this APC and, as a result, the APC payment will not cover the cost of CPT code 43228. We believe this will lead to a reduction in beneficiary access to care for important services. In the case of CPT code 43228, beneficiaries may experience difficulty in accessing endoscopic (non-surgical) treatment of early neoplasia of the esophagus (defined as dysplasia, precancer and early cancer), which, if left untreated, will otherwise progress to invasive esophageal cancer and necessitate esophagectomy.

We continue to believe that creating a new APC for upper GI endoscopy procedures that is intermediate in median cost and facility payment amount between APC 0141 and 0422 would be appropriate.

In response to our comments to the proposed rule, CMS said that it believes that the codes being moved from 0141 to 0422 are similar clinically and in terms of resources to the upper GI procedures in APC 0422. From the perspective of the physicians who deliver these services, we respectfully disagree. Separating the upper GI codes into three separate APCs would create clinical and resource homogeneity. It would also keep all of the endoscopic ultrasound codes together.

Based on the data released with the proposed rule, having three levels of upper GI procedure APCs would significantly tighten the median cost ranges in the APCs. In the three-tiered system as proposed, the Level I APC median costs would range from \$505 to \$691, Level II from \$725 to \$1073, and Level III from \$1329 to \$1868. This contrasts with the final rule’s two-tiered ranges of \$505 to \$1047 and \$1074 to \$1868 for the Level I and Level II APCs, respectively, again using the data released with the proposed rule. With CMS looking to have APCs include procedures with similar medians, these data demonstrate a much higher level of similarity when there are three upper GI procedures APCs as opposed to two APCs.

Therefore, we reiterate our recommendation to create a new Upper GI APC as described below.

Creation of a new APC code that is intermediate in median cost and facility payment between APC 0141 and 0422 would bridge the significant cost gap between APC 0141 and APC 0422, segregate the upper GI endoscopy code family by resource utilization (median cost data, using CMS methodology) and leverage natural breaks in the cost data in order to differentiate codes between Level I (APC 0141), Level II (new), and Level III (APC 0442).

Further, this approach would reassign all endoscopic ultrasound (EUS) codes to a new Level II APC category, which would achieve more resource and clinical homogeneity for this group and eliminate the opportunity for upcoding in EUS services.

UPPER GI LEVEL I (APC 0141) (Proposed three-tier Upper GI APC system)

CPT	Proposed APC	Single Frequency	Mean Cost	Median Cost
43999	0141	1319	\$608.56	\$349.44
43761	0141	363	\$559.42	\$505.32
43235	0141	69,833	\$580.35	\$509.47
43200	0141	995	\$800.06	\$558.99
43239	0141	251,792	\$667.02	\$603.77
43234	0141	414	\$706.88	\$623.31
43248	0141	17,095	\$713.91	\$623.35
43247	0141	4,928	\$727.06	\$623.52
43236	0141	2,983	\$708.61	\$636.14
43202	0141	433	\$915.71	\$642.76
43241	0141	156	\$882.45	\$650.09
43600	0141	7	\$986.47	\$668.95
43243	0141	199	\$795.52	\$684.52
43204	0141	3	\$811.01	\$691.27
43499	0141	464	\$2,304.74	\$1,915.67

UPPER GI LEVEL II (new APC) (Proposed three-tier Upper GI APC system)

CPT	Proposed APC	Single Frequency	Mean Cost	Median Cost
43250	0141	1,055	\$847.14	\$725.40
43201	0141	72	\$1,092.75	\$726.68
43240	0141	29	\$1,244.99	\$746.10
43251	0141	3,039	\$865.61	\$747.05
43458	0141	154	\$919.14	\$754.16
91111	0141	85	\$853.81	\$756.21
43231	0141	281	\$940.57	\$760.14
43259	0141	11,923	\$869.21	\$762.20
43237	0141	422	\$903.09	\$769.45
43205	0141	99	\$856.53	\$769.68
43246	0141	14,755	\$903.85	\$799.65
43215	0141	188	\$1,025.77	\$803.83
44100	0141	5	\$573.69	\$825.31
43255	0141	3,959	\$906.00	\$832.23
49446	0141	279	\$1,116.25	\$843.25
43244	0141	4,551	\$904.83	\$844.69
43249	0141	17,911	\$927.99	\$848.74
43217	0141	38	\$1,035.81	\$894.71
49440	0141	1,558	\$1,094.69	\$902.98
43245	0141	2,266	\$1,013.42	\$905.53
43220	0141	582	\$1,134.04	\$921.75
43226	0141	737	\$1,239.73	\$927.30
49441	0141	126	\$1,221.92	\$944.37
43238	0141	365	\$1,112.77	\$986.79
43232	0141	273	\$1,115.97	\$995.19
43258	0141	4,919	\$1,284.80	\$1,000.70
43227	0141	27	\$1,187.54	\$1,047.13
43242	0422	10,216	\$1,205.13	\$1,073.96

UPPER GI LEVEL III (APC 0422) (Proposed three-tier Upper GI APC system)

CPT	Proposed APC	Single Frequency	Mean Cost	Median Cost
43228	0422	1,602	\$1,976.58	\$1,823.53
43830	0422	168	\$1,866.46	\$1,868.20
43870	0422	108	\$1,594.24	\$1,509.17
43257	0422	57	\$1,511.43	\$1,367.73
43216	0422	16	\$1,506.87	\$1,328.88
C9724	0422	7	\$4,360.09	\$4,451.92
43510	0422	1	\$1,471.40	\$1,471.40

Creating a new Level II APC allows aggregation of codes according to resource homogeneity. The natural breaks are present in the median cost data for the upper GI codes as follows:

	APC	Median Cost (lowest)	Median Cost (highest)
Level I	0141	\$505	\$691
Level II	New	\$725	\$1,073
Level III	0422	\$1,329	\$1,868

Our societies request that CMS reconsider our proposal to create a three-tier APC system for upper GI procedures which would bridge the significant cost gap between APC 0141 and APC 0422, segregate the upper GI endoscopy code family by resource utilization (median cost data, using CMS methodology), and determine appropriate natural breaks in the data in order to differentiate codes between Level I (APC 0141), Level II (new), and Level III (APC 0442). We request that this change be implemented in 2011, retroactively to Jan. 1, 2011 if possible.

Alternative solution to the three-tier upper GI endoscopy APC codes: Assign CPT Code 43228 to APC 0384

Based on the individual median cost figures, one of the codes significantly adversely affected by CMS’s decisions in this final rule is CPT code 43228. **If CMS is unwilling to consider a three-tier upper GI endoscopy APC option as requested above, the effect on CPT 43228 could be rectified in a manner consistent with CMS’s principles by moving CPT code 43228 from APC 0422 to APC 0384.**

Code 43228 is used to report endoscopic procedures for the eradication of esophageal pre-cancer and early cancer with the intent to avoid progression to invasive cancer, to obviate the need for invasive surgery to remove the esophagus, and to lessen the likelihood of cancer-related or surgery-related morbidity and mortality. Endoscopic eradication of esophageal pre-cancer and early cancer fulfills the mandate to achieve better care in a cost-effective manner. CPT code 43228 presently resides in APC 0422. Unfortunately, the reduction in median cost (\$1,137) and facility payment (\$1,149) for APC 0422 in the final rule for 2011 makes it impossible for a hospital to offer CPT code 43228 (median cost \$1,797) in the outpatient setting with this APC payment. This may lead to this procedure being performed in the more expensive hospital inpatient setting instead. It is important for beneficiaries to maintain access to this life-saving technology in the hospital outpatient setting both for the convenience of the patient and because it is more cost-effective to the Medicare system.

As a solution, we propose moving CPT code 43228 to a different existing APC (0384), which is consistent with CMS’s reasoning in the final rule. In the final rule, CMS indicated that a CPT code should be assigned to a new APC when the median costs for the code are “significantly higher” than the median costs for the APC to which it is assigned (75 FR 71907). The final rule median cost of CPT code 43228 is \$1,797. This is \$660 more than the median cost for the APC to which the procedure is assigned (APC 0422 – final rule median cost of \$1,137). This can only be described as a “significantly higher” cost insofar as CMS indicated that \$440 was a significantly higher cost in moving CPT code 43242 from APC 0141 in the final rule for 2011.

Moving CPT code 43228 to APC 0384 is further warranted given CMS’s statements regarding the assignment of CPT codes in the final rule. CMS indicated in the final rule that it was appropriate to reassign a CPT code to a new APC where the median costs for the procedure assigned to that code are

“more consistent with” the median costs of the new APC than the existing APC (75 FR 71908). The final rule median cost for APC 0384 is \$1,895, which clearly is “more consistent with” the final rule median cost for CPT code 43228 of \$1,797 than the final rule median cost for that code is to the median cost for APC 0422 (\$1,137).

Likewise, CMS indicated that where the resources associated with a CPT code are “more similar to” the resources used for the new APC than the existing APC that reassignment to the new APC is appropriate (75 FR 71908). Based on the final rule median cost figures noted above, the resources used in procedures billed under CPT code 43228 are “more similar to” the resources used in procedures in APC 0384 than those in APC 0422.

Finally, CMS stated that it is inappropriate to move a CPT code to a new APC where the median costs of the CPT code and the new APC are “substantially dissimilar” (75 FR 71908) when CMS rejected a request to move CPT code 43240, with a final rule median cost of \$738, into APC 0384. In fact, the median cost of CPT code 43228 is “substantially dissimilar” to the median cost for APC 0422 and is “more similar” to the median cost of APC 0384. Thus, leaving 43228 assigned to APC 0422 is contrary to the agency’s statement that it is not appropriate for a code to be assigned to an APC in which the median cost is substantially dissimilar. This would not be the case if CPT code 43228 were assigned to APC 0384 given the less than \$100 difference between the final rule median costs for CPT code 43228 and APC 0384.

The table below shows the single frequency claim count and median cost based on the proposed and final rules for APC 0141, 0384, and 0422 as well as the final rule payment rate.

APC	Proposed Rule 2011		Final Rule 2011		
	Single Frequency Claims	Median Cost	Single Frequency Claims	Median Cost	Payment Rate
0141	422,003	\$623.18	448,045	\$605.22	\$611.73
0384	7,181	\$1,919.39	7,710	\$1,895.04	\$1,915.43
0422	12,214	\$1,143.75	13,397	\$1,136.52	\$1,148.75

The table below shows the impact to single frequency claim count, median cost and projected payment rate for 2011 upon moving CPT code 43228 from APC 0422 to APC 0384; note that there is no impact to APC 0141.

APC	Single Frequency Claims	Median Cost	Projected Payment Rate
0141	422,003	\$623.18	\$611.73
0384	8784	\$1,902.23	\$1,898.31
0422	10611	\$1,089.73	\$1,094.49

Again, the GI societies register concern about the final rule's impact on beneficiary access to care for CPT code 43228 and recommend that CMS could immediately rectify this in a manner consistent with CMS's principles by moving CPT code 43228 from APC 0422 to APC 0384.

Assigning the Smart Pill GI Monitoring System to an APC

The SmartPill GI Monitoring System measures the whole gut and regional gut transit times. Measurement of GI tract transit times is used for evaluating motility disorders. The system utilizes a wireless motility capsule (WMC) which measures pH, temperature, and pressure. Pressure contraction data from the antrum and duodenum can be used to calculate motility indices.

Motility refers to the capability of moving spontaneously. While the WMC measures transit, pH, temperature and pressure, it does not measure the neuromuscular activity of the specific GI luminal structure that cause food and chyme to be propelled.

The SmartPill GI monitoring system is different from a resource utilization and clinical perspective from other motility tests in APC 0361, which solely measure the functionality of the gut muscles.

Through Dec. 31, 2010, this procedure is reported using code 91299, unlisted diagnostic gastroenterology procedure. Code 91299 is in APC 0360, Level I Alimentary Tests, with a 2010 payment rate of \$120.13. Beginning Jan. 1, 2011, the procedure will be reported using code 0242T (Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report), which CMS has assigned to APC 0361, Level II Alimentary Tests, with a 2011 payment rate of \$282.48. **The GI societies are requesting that this code be assigned to a New Technology Level X, APC 1510, because we do not believe that APC 0361 is the appropriate APC to report this procedure under the hospital outpatient prospective payment system (HOPPS).**

Because 0242T is a new category III code, there are no claims data to adequately determine the appropriate resource use of this service. The equipment and disposable supply resources used for this procedure include:

- SmartPill WMC Capsule and SmartBar meal necessary to induce fed state and to measure gastric emptying in a fasting patient, Smart Pill event diary (disposable, invoice price \$600)
- SmartPill laptop/Motilit-GI software, SmartPill Receiver, and Docking Station system with battery charger, pH buffer calibration solution, WMC capsule Activation magnet (equipment, invoice price \$20,000)

The above does not include the clinical staff labor required to assess the patient, hook the patient up to SmartPill Receiver system, provide immediate supervision of the patient post WMC ingestion, provide instructions to the patient, call the patient daily to check on the patient's symptoms and tolerability of WMC, remove the Receiver system at the conclusion of procedure, download the data using the Docking Station, and prepare the raw data findings for physician interpretation.

The disposable resource costs for the WMC Capsule and the SmartBar meal alone are \$600 per procedure, which is more than two times the payment rate for APC 0361. Keeping this new technology in APC 0361 would negatively impact beneficiaries through limited access to this procedure, the only test that provides complete evaluation of the gastrointestinal tract transit, pressure, pH and temperature from the stomach to the anus. In addition, this test is reproducible, has inter-rater reliability, and does not expose the beneficiary to any radiation whether from computed tomography, fluoroscopy, and/or nuclear scintigraphy studies.

As noted above, the payment rate of \$282.48 for APC 0361 is 53% below the costs of the disposable supplies associated with this procedure, which does not take into account the costs of the equipment and clinical staff needed to perform the procedure. When all costs are accounted for, the payment gap for this procedure would be even greater, and violates the 2-times rule for this APC. In view of the costs of the procedure, assigning HCPCS code 0242T to APC 0361 would significantly impact utilization and would hamper the ability of CMS to effectively gauge the appropriate costs and resource use for both this procedure, as well as all procedures currently in APC 0361.

We believe that code 0242T should be assigned to New Technology Level X, APC 1510, because it is not clinically similar to the existing procedures in APC 0361. Code 0242T, *Gastrointestinal tract transit and pressure measurement, stomach through colon, wireless capsule, with interpretation and report*, is significantly different from other procedures in APC 0361.

The procedures in APC 0361 predominantly assess the esophagus (codes 91010, 91011, 91012, 91013, 91030, 91034, 91035, 91037, 91038) or stomach (91020, 91022, 91052). In contrast, code 0242T does not assess the esophagus at all. Rather, it is a unique test that provides transit, pressure, pH, and temperature measurement of the GI tract from the stomach to the anus.

The resource and clinical labor for the currently existing procedures in APC 0361 are different from code 0242T.

The manometric tests in APC 0361 (91010, 91011, 91012, 91013) measure neuromuscular activity in an anatomically-specific, fixed manner, and utilize a reusable catheter. In contrast, code 0242T uses a disposable capsule to capture multiple pressure and transit measurements throughout the GI tract, as it is essentially impossible to measure neuromuscular activity of the small intestine using catheter-based technology.

The esophageal reflux tests in APC 0361 (91034, 91035, 91037, 91038) measure esophageal pH in an anatomically-specific, fixed manner. These tests only measure esophageal pH, and do not measure gastric, small or large intestinal pH. In contrast, code 0242T uses a disposable capsule to capture multiple pH data throughout the GI tract, which is correlated with transit measurements and symptoms to identify the patient's diagnosis and develop a specific treatment plan based on real-time findings.

The esophageal reflux tests in APC 0361 utilize the esophageal pH data as a direct measurement. In contrast, the pH data captured by code 0242T is used to verify capsule location in the GI tract and to determine specific transit times. The transit times are then used by the physician to make a diagnosis and develop a treatment plan.

While the intent of CMS might have been to place code 0242T with code 91035 because of a "wireless capsule" terminology, we note that code 91035 requires implantation of the capsule into the esophagus and eventual sloughing off of the capsule, while code 0242T utilizes a capsule which is ingested, not implanted. Clinically these two procedures are quite different.

We recognize that it can be challenging to properly assign new procedures APCs with clinical and resource similarities. When one adds the supplies, equipment, and clinical labor necessary to perform this diagnostic test, we come up with a cost estimates in excess of \$800. Based on the direct costs necessary to perform this procedure, we believe that this procedure should be placed into a New Technology Level X (\$800-\$900), APC 1510, with a median payment of \$850. Placement into a New Technology APC will allow for adequate and consistent payments for this new technology and will allow CMS to capture the cost data necessary until such a time that claims data is sufficient to assign this procedure to an APC.

From a historical perspective, placement of code 0242T into New Technology APC 1508 is consistent with past CMS determinations concerning ingestible diagnostic wireless capsule technology with similar resource use. For example, in January 2004 CMS assigned code 91110, gastrointestinal tract imaging, intraluminal (eg, capsule endoscopy), esophagus through ileum, with physician interpretation and report, to New Technology APC 1508 with a payment rate of \$650. Subsequently, based on “almost 4,000 single claims...available for use in calculating the median cost of the service”, in January 2005 CMS moved code 91110 to APC 0142, Small Intestine Endoscopy, which accurately reflects the equipment, clinical labor and disposable supplies necessary to perform this procedure.

Based on the resource costs for code 0242T, the GI societies believe that New Technology APC 1510 would be the most appropriate APC for the SmartPill GI monitoring system procedure.

Method of Updating ASCs

We are also disappointed that CMS will continue to use the most recent available raw pre-floor and pre-reclassified hospital wage indices to adjust the labor portion of ASC costs. By continuing to use the pre-floor, pre-reclassified hospital wage indices to calculate individual ASC payments, it exacerbates at the local level the growing variation between ASC and HOPPS payments. As has been requested in the past by the gastrointestinal community and other ASC stakeholders, **we ask that CMS reevaluate this issue for 2012 and reconsider using the same “adjusted” hospital wage indices for calculating ASC payments as it uses for the HOPPS payments.**

For 2011, CMS finalized its proposal to create relative weights for use in setting ASC payments through a secondary rescaling of the HOPPS relative weights. This rescaling occurs even though the APC relative weights are rescaled once for budget neutrality under the HOPPS rules. For 2011, ASC payments may fall below 57 percent of the HOPD payment as a result. **We ask that CMS re-evaluate its policy of secondary rescaling and, in the future, use its administrative authority to not apply secondary rescaling.**

Our societies are dismayed that CMS has again decided to use the consumer price index for urban consumers (CPI-U) as the update factor for calculating CY2011 ASC payments. The hospital market basket is a much more appropriate measure of ASC cost inflation than an index measuring changes in the costs of goods and services purchased by consumers. The hospital market basket is used to adjust the HOPPS, and reflects the same types of operating costs faced by ASCs. **As we have commented to CMS numerous times, we urge CMS to reconsider updating ASC payments using the hospital market basket index in the future.**

Conclusion

Thank you for the opportunity to offer these comments. We welcome a meeting with CMS staff to discuss our recommendations. If we may provide any additional information, please contact Anne Marie Bicha, Director of Regulatory Affairs, AGA, at 240-482-3223, or abicha@gastro2.org; Brad Conway, Vice President of Public Policy, ACG, at 301-263-9000, or bconway@acg.gi.org; or Camille Bonta, consultant to ASGE at 202-320-3658 or cbonta@asge.org.

Sincerely:

Handwritten signature of Gail A. Hecht, MD in cursive script.

Gail A. Hecht, MD, AGAF
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