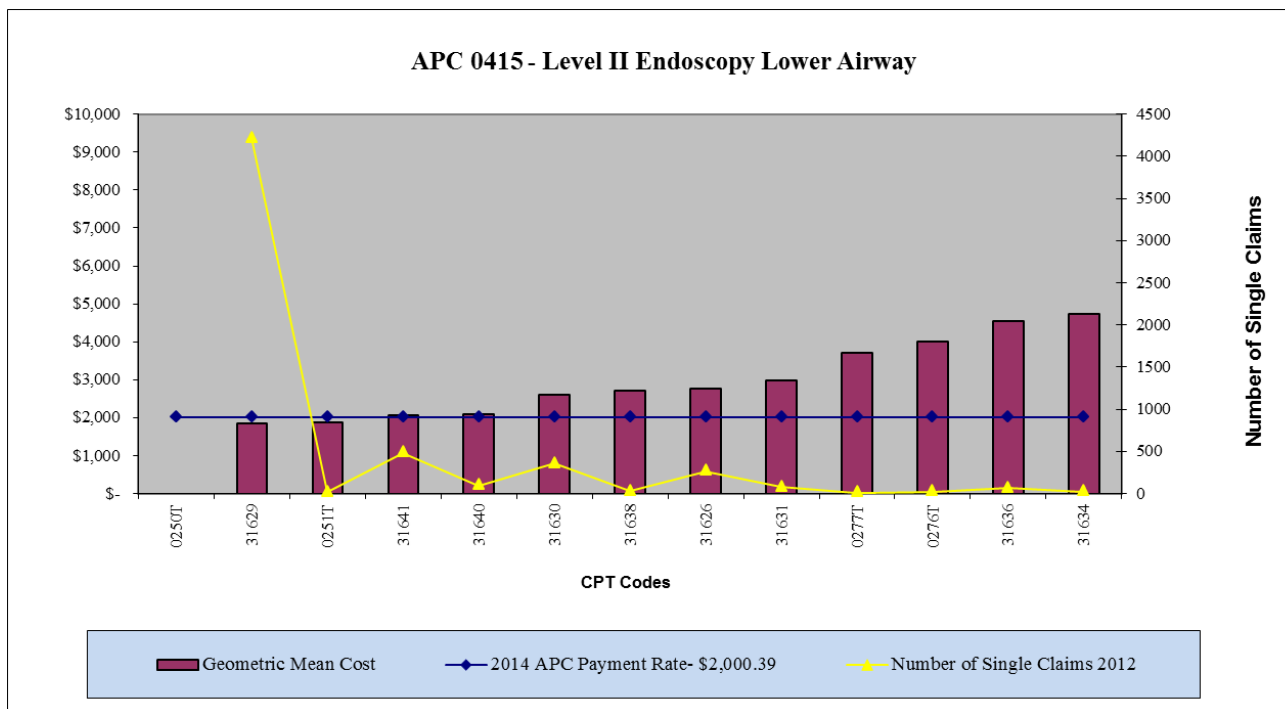


OPPS Payment for Advanced Bronchoscopy Procedures

Presented by: Maria Stewart, Boston Scientific Corporation
March, 2014 APC Advisory Committee Meeting
CMS Central Office, Baltimore, MD
March 10-11, 2014

- APC 0415 contains a mix of bronchoscopy procedures characterized by highly varied complexity and geometric mean costs, resulting in significant underpayment of more clinically complex and resource-intensive procedures.
- Procedures most negatively impacted are critical for indicated patients, who often have few if any alternative treatment options.



Realign Endoscopy Lower Airway APCs to better recognize differences in cost and clinical complexity for the most advanced, resource intense bronchoscopy procedures currently assigned to APC 0415 (Level II Endoscopy Lower Airway).

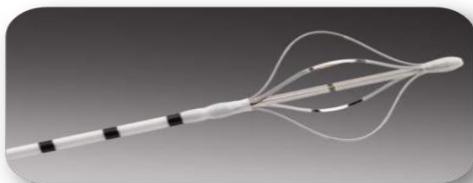
- Specifically, create a Level III Endoscopy Lower Airway APC, moving several complex procedures including (but not limited to) bronchial thermoplasty to:
 - Improve clinical homogeneity across Endoscopy Lower Airway APCs;
 - Better reflect the more intense resource use and costs of procedures using implants and advanced catheters;
 - Improve payment precision; and
 - Remove payment barriers to patient access.

What is Bronchial Thermoplasty?

The Alair® Bronchial Thermoplasty System delivers controlled thermal energy to the airway via a bronchoscope to reduce airway smooth muscle

- Approved by the FDA for the treatment of severe persistent asthma in patients 18 years and older whose asthma is not well controlled with inhaled corticosteroids and long acting beta agonists
- Designed to inhibit airway constriction that occurs in asthma
- Most commonly performed in the hospital outpatient setting

The Alair® Catheter is a flexible tube with an expandable wire array at the tip



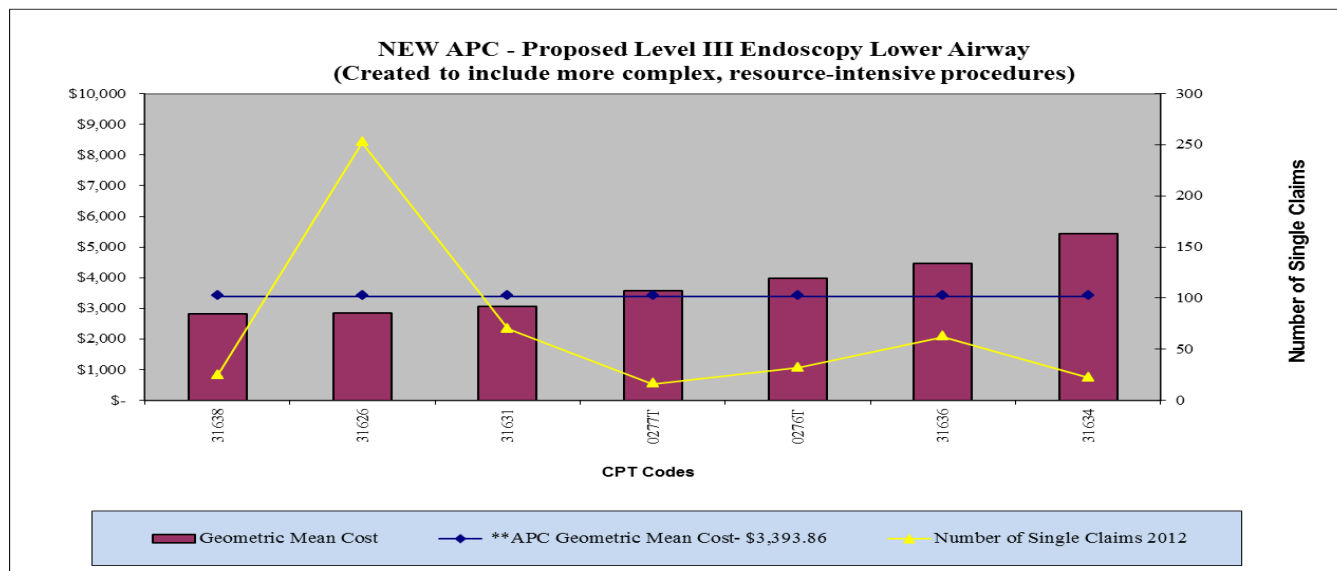
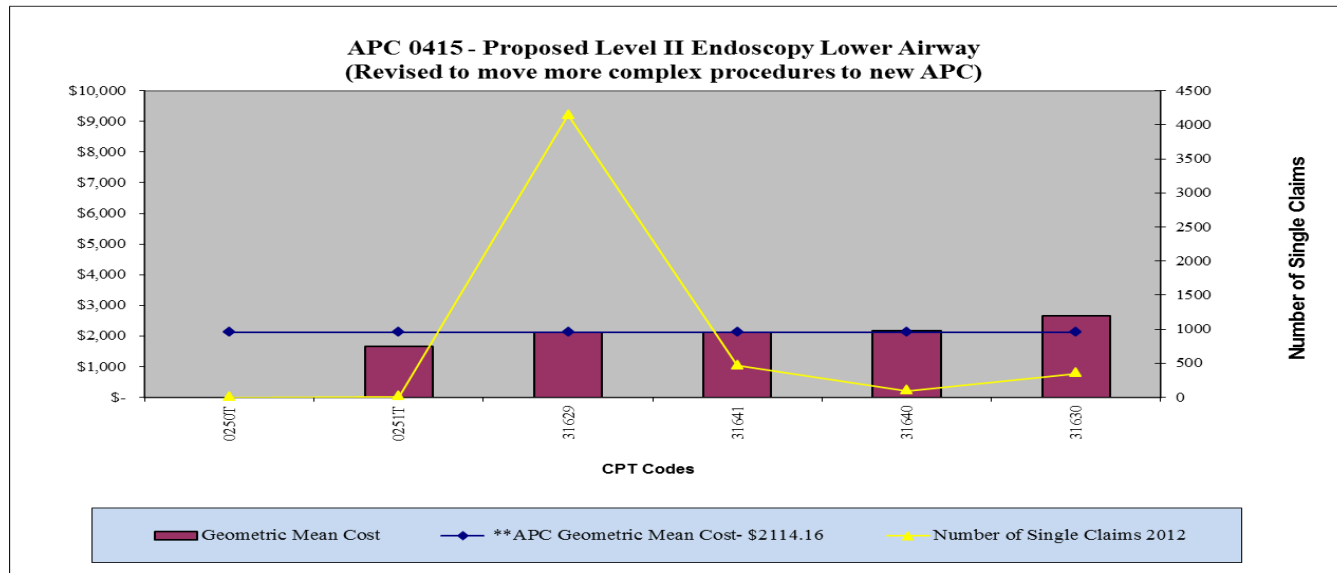
The Alair® Radiofrequency Controller supplies energy via the catheter to heat the airway wall



Complex Bronchoscopies: Review of Clinical and Resource Characteristics

HCPSC Code	Descriptor	Implant / Specialized Device?	High Clinical Complexity	Resource Intensive?
0250T	Bronchial valve init insert	✓ - Valves	✓	✓
31629	Bronchoscopy/needle bx each			
0251T	Bronchial valve remov init			
31641	Bronchoscopy treat blockage			
31640	Bronchoscopy w/tumor excise			
31630	Bronchoscopy dilate/fx repr			
31638	Bronchoscopy revise stent	✓ - Stent(s)	✓	✓
31626	Bronchoscopy w/markers	✓ - Marker(s), navigation	✓	✓
31631	Bronchoscopy dilate w/stent	✓ - Stent(s)	✓	✓
0277T	Bronch thermoplasty 2/> lobe	✓ - RF Catheter, Capital	✓	✓
0276T	Bronch thermoplasty 1 lobe	✓ - RF Catheter, Capital	✓	✓
31636	Bronchoscopy branch stents	✓ - Stent(s)	✓	✓
31634	Bronch w/balloon occlusion	✓ - Fibrin sealant	✓	✓

Impact of Level III Endoscopy Lower Airway APC



Rationale for Level III Endoscopy Lower Airway APC

- Affords greater clinical and resource homogeneity
- Allows for more precise reflection of true costs of more complex bronchoscopy procedures
- No impact to APC 0076
- Minimal impact on bronchoscopy spending and overall OPPS spending
- Removes payment as potential barrier to access
- Strong precedent exists
 - ~44 procedure families have ≥ 3 levels of procedural APCs, often with substantial differences in claims volumes across the levels
 - Example: Laparoscopy has 4 levels; highest volume level has 91,210 single frequency claims; lowest volume level has 165 single frequency claims
 - In all, 21 APCs in the 2014 OPPS Final Rule have ≤ 500 single frequency claims (35 APCs have $\leq 1,000$ single frequency claims)
 - Level III Endoscopy Lower Airway APC likely to have between 500 and 1,000 single frequency claims

Conclusion

- Creation of a Level III Endoscopy Lower Airway APC would:
 - Improve clinical homogeneity across Endoscopy Lower Airway APCs;
 - Better reflect the more intense resource use and costs of procedures using implants and advanced catheters;
 - Improve payment precision; and
 - Remove payment barriers to patient access.
- Precedents exist for creation of additional APC levels of lower volume.
 - In 2014, CMS created APC 0431, Level IV Closed Treatment Fracture, with a single frequency claim volume of 439 claims.
- Alternative options address some, but not all, payment discrepancies.

Thank You!

Backup Slides

Coding Clarification

Several codes in APCs to be discussed changed from 2012 to 2013 / 2014. The following table summarizes changes:

2012 CPT Code	Short Descriptor	2014 CPT Code
0250T	Bronchial valve init insert	31647
0251T	Bronchial valve remov init	31648
0252T	Bronchial valve remov addl	31649
0276T	Bronch thermoplasty 1 lobe	31660
0277T	Bronch thermoplasty 2/> lobe	31661
31656	Bronchoscopy inj for x-ray	n/a; report with 31899

Since 2012 Medicare claims data are the latest available, in all following tables refer to 2012 codes and associated data.

2014 OPPS Payment for Endoscopy Lower Airway Procedures (Current)

APC	HCPCS	Descriptor	Payment Rate	Single Frequency	Total Frequency	Geometric Mean Cost	Deleted Code Used in APC Costs
0076	Level I Endoscopy Lower Airway		\$951.62	28,786	109,737	\$954.95	
0076	0252T	Bronchial valve remov addl			6		YES
0076	31646	Bronchoscopy reclear airway	\$951.62	76	127	\$567.26	
0076	31645	Bronchoscopy clear airways	\$951.62	1618	3405	\$752.21	
0076	31622	Dx bronchoscope/wash	\$951.62	9134	17729	\$839.26	
0076	31643	Diag bronchoscope/catheter	\$951.62	137	381	\$898.88	
0076	31623	Dx bronchoscope/brush	\$951.62	3399	21069	\$971.06	
0076	31899	Airways surgical procedure	\$951.62	223	712	\$975.94	
0076	31624	Dx bronchoscope/lavage	\$951.62	8299	32282	\$993.57	
0076	31625	Bronchoscopy w/biopsy(s)	\$951.62	3290	13580	\$1,137.65	
0076	31628	Bronchoscopy/lung bx each	\$951.62	2611	19769	\$1,192.64	
0076	31635	Bronchoscopy w/fb removal	\$951.62	220	666	\$1,315.50	
0076	31656*	Bronchoscopy inj for x-ray		2	11	\$1,381.36	YES
0415	Level II Endoscopy Lower Airway		\$2,000.39	5,669	17,993	\$2,007.40	
0415	0250T	Bronchial valve init insert			5		YES
0415	31629	Bronchoscopy/needle bx each	\$2,000.39	4215	13259	\$1,855.57	
0415	0251T	Bronchial valve remov init		17	30	\$1,872.82	YES
0415	31641	Bronchoscopy treat blockage	\$2,000.39	486	1510	\$2,064.99	
0415	31640	Bronchoscopy w/tumor excise	\$2,000.39	98	304	\$2,104.53	
0415	31630	Bronchoscopy dilate/fx repr	\$2,000.39	358	1343	\$2,611.66	
0415	31638	Bronchoscopy revise stent	\$2,000.39	28	61	\$2,711.12	
0415	31626	Bronchoscopy w/markers	\$2,000.39	266	889	\$2,755.29	
0415	31631	Bronchoscopy dilate w/stent	\$2,000.39	76	185	\$2,993.45	
0415	0277T	Bronch thermoplasty 2/> lobe		13	51	\$3,700.18	YES
0415	0276T	Bronch thermoplasty 1 lobe		25	92	\$4,018.54	YES
0415	31636	Bronchoscopy bronch stents	\$2,000.39	66	234	\$4,538.20	
0415	31634	Bronch w/balloon occlusion	\$2,000.39	21	30	\$4,721.23	

Source: Costs for Hospital Outpatient Services, by APC Group and CPT for CY 2014, 01/16/2014.

* 31656 deleted for 2014. Now reported using 31899.

Review of APC 0415 Procedures*

Procedure Type and Indication	Resources / Complexity	Staff / Resources Required	Procedural Alternatives
Airway Stenting (31631, 31636, 31638) <ul style="list-style-type: none"> • Compression or strictures due to tumors • Stenosis of the central airways • Tracheo-esophageal fistula, airway complications 	High	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 2 • Anesthesia: 1 • Devices: Fluoroscopy, Stent(s), Balloon(s) 	Surgery
Bronchial Thermoplasty (0276T, 0277T) <ul style="list-style-type: none"> • Severe persistent asthma not well controlled on ICS, LABA 	High	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 2 • Anesthesia: 1 • Devices: BT Controller and Catheter 	None
Balloon Occlusion (31634) <ul style="list-style-type: none"> • Tracheo-esophageal fistula 	High	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 1 • Anesthesia: 1 • Devices: Balloon(s), Fibrin Sealant 	Surgery
Fiducial Placement (31626) <ul style="list-style-type: none"> • Treatment planning 	High	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 2 • Anesthesia: 1 • Devices: Navigation, Fiducials 	n/a
TBNA / EBUS (31629) <ul style="list-style-type: none"> • Biopsy of suspect lesions 	Moderate	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 2 • Anesthesia: 1 • Devices: EBUS, Aspiration Needle 	Surgery
Dilation (31630) <ul style="list-style-type: none"> • Stenosis • Occlusions 	Moderate	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 1 • Anesthesia: 1 • Devices: Balloon(s) 	None or Stenting
Excision / Removal (31640, 31641) <ul style="list-style-type: none"> • Small lesions 	Moderate	<ul style="list-style-type: none"> • Physician: 1 • Nurse / Technicians: 1 • Anesthesia: 1 • Devices: Forceps, scalpel or RFA catheter, Basket (?) 	Surgery

*Bronchial valves not addressed because they are too new.

Precedents for Multi-Level Procedural Groups

Approximately 44 procedure groups in the 2014 OPPS Final Rule have ≥ 3 levels (see sample table below).

- In some cases there are substantial differences in claims volumes among the APCs in a procedure group.

Group Title	Number of Levels	Highest Single Claim Volume	Lowest Single Claim Volume
Anterior Segment Eye Procedures	7	7,521	26
ENT Procedures	7	18,727	1,625
Debridement & Destruction	5	646,363	3,919
Endoscopy Upper Airway	5	77,118	485
Repair and Plastic Eye Procedures	5	87,675	1005
Anal / Rectal Procedures	4	10,992	2,831
Breast and Skin Surgery	4	38,318	1,057
Eye Tests & Treatments	4	295,171	844
Laparoscopy	4	91,210	165
Musculoskeletal Procedures Ex. Hand/Foot	4	22,211	8,507
Urinary and Anal Procedures	4	58,020	2,831
Closed Treatment Fracture	4	12,102	439
Audiometry	3	122,863	12,721
Incision & Drainage	3	40,301	1,891
Posterior Segment Eye Procedures	3	43,781	560
Sigmoidoscopy and Anoscopy	3	22,742	434
Upper GI Procedures	3	397,825	2,864

Source: CMS OPPS 2014 Final Rule, Cost Statistics File, January 16, 2014.

Precedents for Low Volume APCs

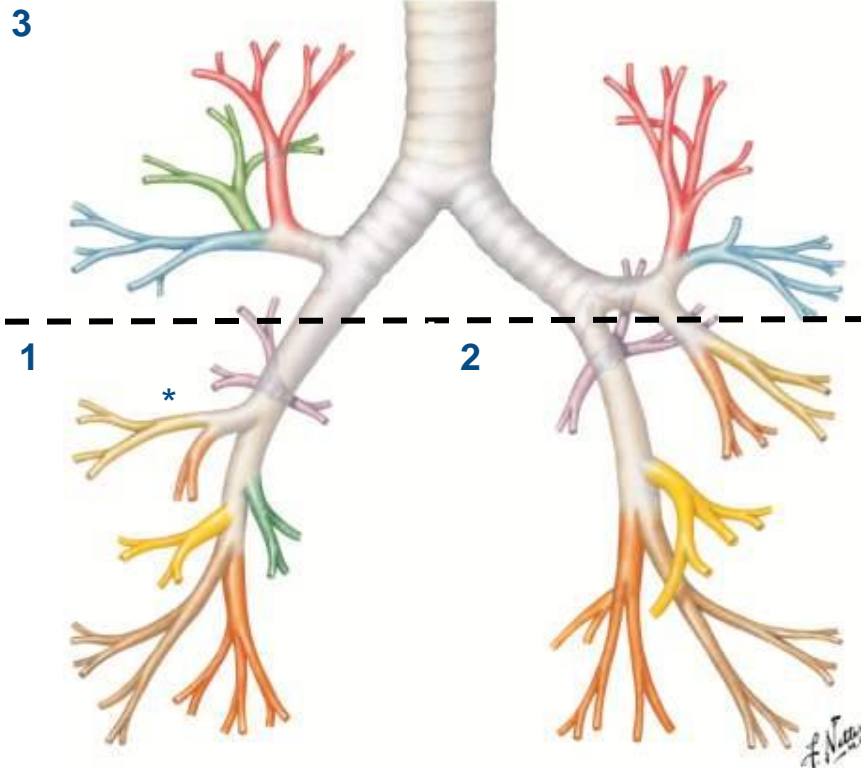
In all, 21 APCs in the 2014 OPPS Proposed Rule have ≤ 500 single frequency claims (35 APCs have $\leq 1,000$ single frequency claims).

APC	Descriptor	Payment Rate	Single Frequency	Geometric Mean Cost
0442	Dosimetric Drug Administration	\$ 1,822.34	6	\$ 1,828.73
0205	Level III Male Genital Procedures	\$ 3,553.44	354	\$ 3,565.88
0351	Level VII Anterior Segment Eye Procedures	\$ 15,551.23	33	\$ 15,605.69
0312	Radioelement Applications	\$ 361.29	52	\$ 362.55
0065	IORT, MRgFUS, and MEG	\$ 1,248.28	94	\$ 1,252.65
0413	Level II Radionuclide Therapy	\$ 356.68	93	\$ 357.93
0157	Colorectal Cancer Screening: Barium Enema	\$ 289.96	148	\$ 290.97
0293O	Level VI Anterior Segment Eye Procedures	\$ 7,697.92	24	\$ 7,724.88
0174	Level IV Laparoscopy	\$ 8,593.40	165	\$ 8,623.49
0403	Level I Nervous System Imaging	\$ 162.68	189	\$ 163.25
0375O	Ancillary Outpatient Services When Patient Expires	\$ 6,913.33	267	\$ 6,937.54
0651	Complex Interstitial Radiation Source Application	\$ 997.90	90	\$ 1,001.39
0381O	Single Allergy Tests	\$ 34.96	104	\$ 35.08
0393	Hematologic Processing & Studies	\$ 565.95	323	\$ 567.93
0153	Peritoneal and Abdominal Procedures	\$ 1,836.39	339	\$ 1,842.81
0115O	Cannula/Access Device Procedures	\$ 2,842.37	431	\$ 2,852.32
0431	Level IV Closed Treatment Fracture	\$ 1,252.15	439	\$ 1,256.54
0152	Level I Percutaneous Abdominal and Biliary Procedures	\$ 1,788.36	416	\$ 1,794.62
0075	Level V Endoscopy Upper Airway	\$ 3,051.76	485	\$ 3,062.44
0428	Level III Sigmoidoscopy and Anoscopy	\$ 1,657.13	434	\$ 1,662.93
0370	Multiple Allergy Tests	\$ 41.33	488	\$ 41.48

Source: Costs for Hospital Outpatient Services, by APC Group for CY 2014, 01/16/2014

Bronchial Thermoplasty Treatment Method

- The Alair® system is designed for the treatment of the airways distal to the mainstream bronchi down to airways of 3mm in diameter²
- Procedure is performed by a trained physician over three treatment sessions, each scheduled approximately three weeks apart and treating a different section of the lung²
- Each session is approximately 45-60 minutes³



- 1st procedure: right lower lobe⁴
- 2nd procedure: left lower lobe⁴
- 3rd procedure: both upper lobes⁴

Note: Right median lobe (RML) is not currently treated with BT