Noah Medical

U.S. Reimbursement and Coding Guide for Select Bronchoscopy Procedures

Medicare National Payment Rates

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What is TPT?

- The TPT Program was created and is administered by the Centers for Medicare and Medicaid Services (CMS) under the Medicare Hospital Outpatient Prospective Payment System[1]
- It is intended to facilitate Medicare beneficiary access to new and innovative medical devices that meet various criteria
- The TPT Program provides incremental payment in addition to the standard Medicare hospital outpatient Ambulatory Payment Classification (APC) payment, to account for the cost of qualifying technologies when utilized in qualifying procedures

What went into effect on January 1, 2024?

- CMS awarded TPT status to qualifying single-use pulmonary bronchoscopes utilized in select procedures[2]
- To facilitate TPT payment, CMS created a new device category and corresponding HCPCS code for hospital outpatient billing
- The TPT designation lasts for three years and provides incremental payment during that period

What is the new HCPCS code and device category?

- HCPCS code: **C1601**
- Device category: Endoscope, single-use (i.e., disposable), pulmonary, imaging/illumination device (insertable)

How do hospitals indicate to CMS that a TPT device was utilized in a procedure?

- HCPCS code C1601 must be included on the hospital outpatient claim when a qualifying device is used in a qualifying bronchoscopic procedure.
- The hospital must determine its own charges for C1601, and include them on the hospital outpatient claim submitted to CMS.

What devices qualify for TPT under C1601?

- Once CMS creates a new TPT device category, that category applies to all devices that are described by the code's long descriptor and CMS' general explanations that accompany coding assignments, and that meet the criteria for TPT. Once created, a device category does not necessarily apply to only a single device.
- Further, CMS does not have to have qualified a particular device for transitional pass-through payment before a hospital can bill for the device. Hospitals are expected to make appropriate coding decisions based on CMS instructions and other information available to them.[1]

Does the Galaxy Bronchoscope qualify for TPT under C1601 when utilized with the Galaxy System?

- Noah Medical has done extensive analysis and research, including securing an independent third-party [expert] analysis from a law firm, and has concluded that the Galaxy Bronchoscope appears to meet the C1601 device category and is therefore eligible for TPT

[1]Medicare Claims Processing Manual, Chapter 4 § 60.2
[2] Transmittal 12421, Change Request 13488, Dec. 21, 2023, https://www.cms.gov/files/document/r12421cp.pdf

Transitional pass-through (TPT) payment status for single-use pulmonary bronchoscopes FAQ

- However, this should not be construed as legal guidance or advice, as each provider should make their own determination as to the applicability of C1601 to any single-use bronchoscope
- Note: A hospital can request guidance from its Medicare Administrative Contractor (MAC) about use of a particular code

Are there specific procedures (e.g., CPT codes) that are eligible for TPT when a device described by C1601 is utilized?

- Yes – in its decision, CMS listed 39 CPT codes that can be billed with C1601 and qualify for TPT. CMS has published the list of procedures at https://www.cms.gov/files/document/r12421cp.pdf.[2]
- Please note that not all of these procedures may be appropriate for use with the Galaxy Bronchoscope and System.

How is the TPT payment determined?

- The incremental TPT payment is calculated at the hospital level
- CMS estimates the cost of the new device by multiplying the hospital charges for C1601 by the hospital's cost-to-charge-ratio for the revenue center, Implantable Devices Charged to Patients
- This calculated cost is reduced by the device offset that is established by CMS for each procedure – the device offset for each procedure is listed at https://www.cms.gov/files/document/r12421cp.pdf
- Once the device offset is removed, the remaining balance is what should be paid to the hospital in addition to the appropriate APC payment to which the procedure(s) performed is assigned

Does the TPT apply to all payers?

- The TPT program was established and is administered by CMS, and applies to Medicare Fee-For-Service beneficiaries
- For Medicare Advantage patients, we recommend consulting with the hospital contact or the Medicare Advantage payer directly to determine if hospital payment is adjusted for TPT
- Similarly, for non-Medicare patients, we recommend consulting with the payer-specific contact, or the payer directly to determine if their hospital payment is adjusted for TPT

What reimbursement resources are available from Noah Medical?

- We are happy to do our best to answer your reimbursement questions related to the Galaxy System.
- Noah Medical offers a reimbursement guide with the coding and Medicare payment information for the Galaxy System. Contact your sales representative or request the reimbursement guide at reimbursement@noahmed.com.
- Should you have additional questions, please email Noah Medical at reimbursement@noahmed.com for a prompt response

[2] Transmittal 12421, Change Request 13488, Dec. 21, 2023, https://www.cms.gov/files/document/r12421cp.pdf

Transitional pass-through (TPT)

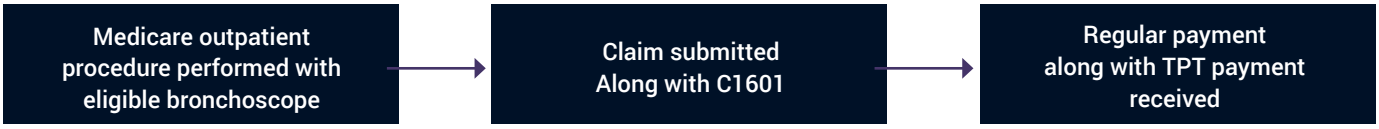
Payment overview

The TPT Program is intended to facilitate Medicare beneficiaries' access to new and innovative medical devices. The TPT Program provides incremental payment in addition to the standard Medicare hospital outpatient Ambulatory Payment Classification (APC) payment for the related procedure.

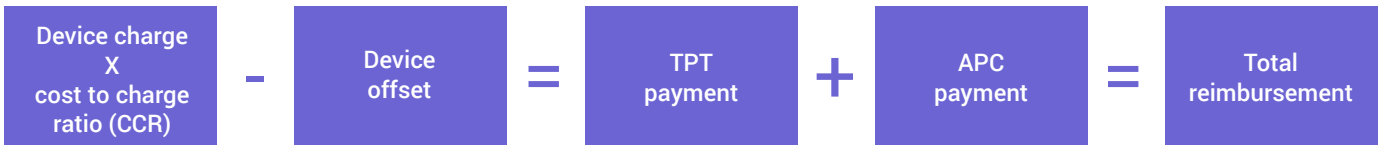
TPT and disposable pulmonary bronchoscopes

- Effective January 1, 2024, CMS awarded TPT status to qualifying single-use pulmonary bronchoscopes utilized in select procedures[1]
- Each hospital is responsible for determining whether a particular device qualifies for TPT payment.
- A third-party legal analysis concluded that the Galaxy Bronchoscope appears to meet the criteria for TPT payment.[2]
- This status is set to last for three years
- C1601 expires on December 31, 2026

Coding process



The calculation



Complexity adjusted example using primary and secondary CPT codes 31629 + 31628* (For illustrative purposes only)

	Element	Calculation	Amount
Hospital charges for C1601	A		$7,500
Hospital implantable devices CCR	B		0.2689
Reported cost of C1601	C	A x B	**$2,017**
Device-related offset of CPT code 31629	D		$45
Incremental TPT payment	E	C - D	**$1,972**
APC assignment for CPT codes 31629 + 31628 (APC5155)	F		$6,922
Total APC + TPT payment	G	E + F	**$8,894**

*CPT 31628 and 31629 are two of several procedural codes that can be billed with C1601. The full list of procedures is in Transmittal 12421, Change Request 13488, Dec. 23, 2023, https://www.cms.gov/files/document/r12421cp.pdf.

1) Transmittal 12421, Change Request 13488, Dec. 21, 2023, https://www.cms.gov/files/document/r12421cp.pdf

2) https://noahmedical.showpad.com/share/CCU2m6iJp7egXScz6y3s4

Terminology and abbreviations

Reimbursement terminology used in this guide is briefly defined below. Unless otherwise noted, all definitions and sources are available at the Centers for Medicare and Medicaid Services (CMS) Glossary: www.cms.gov/apps/glossary/.

American Medical Association (AMA): Professional organization for physicians that maintains the Physicians' Current Procedural Terminology (CPT) coding system.

Ambulatory Payment Classification (APC): Developed by CMS as the basis for hospital outpatient reimbursement rates. Relevant CPT codes are grouped into APCs based on resource utilization.

Comprehensive Ambulatory Payment Classification (C-APC): Identified by the status indicator of J1, C-APC's provide a single payment for most services provided during the hospital outpatient admission. The single payment for a comprehensive claim is based on the rate associated with the J1 service. When multiple J1 services are reported on the same claim, the single payment is based on the rate associated with the highest-ranking J1 service. When certain pairs of J1 services (or in certain cases a J1 service and an add-on code) are reported on the same claim, the claim is eligible for a complexity adjustment, which provides a single payment for the claim based on the rate of the next higher comprehensive APC within the same clinical family. Note that complexity adjustments will not be applied to discontinued services (reported with modifier -73 or -74).

Centers for Medicare and Medicaid Services (CMS): Federal government agency within the Department of Health and Human Services that administers public health programs. (Refer to Prospective Payment System).

Procedural terminology (CPT codes): Fee schedule: List of codes and services with payment amounts (also referred to as reimbursement rates).

Medicare physician fee schedule (MPFS): Annual fee schedule published by CMS based on work, expense, and malpractice designed to standardize physician payment. Multiple procedure payment indicators: 0-3 amended to certain procedures when occurring simultaneously and reflects reduced payment based upon the overlap of the pre- and post-procedure work. This applies to physician reimbursement for services performed.

Prospective payment system (PPS): A method of reimbursement in which Medicare payment is made based on a predetermined, fixed amount. The payment amount for a particular service is derived based on the classification system of that service (for example, APCs for outpatient hospital services).

Transitional pass-through payment status (TPT): This is a program applicable to Medicare Fee-For-Service patients where CMS may provide incremental hospital payment for qualifying device categories. The intent of the TPT is to facilitate access for Medicare patients to the advantages of new and truly innovative devices.

Physician coding and billing information

The following coding information is intended for educational purposes only; reimbursement will vary depending on services rendered. Providers may choose to perform multiple procedures on the same date or service; packaging and multiple procedure rules are applied based on the procedures performed. Providers should report all procedures performed. Please consult your internal coding and compliance guidelines.

Bronchoscopy with biopsy

CPT® code	CPT® description:	2025 Total non-facility RVUs	2025 MPFS non- facility payment	2025 total facility RVUs	2025 MPFS facility payment	MPPI**
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)	7.52	$243	3.90	$126	2
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings	8.18	$264	3.88	$125	3
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage	7.65	$247	3.94	$127	3
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites	10.33	$334	4.58	$148	3
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple	22.85	$739	5.84	$189	2
31628*	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe	10.89	$352	5.15	$167	3
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s) trachea, main stem and/or lobar bronchus	13.30	$430	5.49	$178	3

CMS-1784-F; https://www.cms.gov/medicare/physician-fee-schedule/search, accessed December 29, 2023

Physician coding and billing information

Computer assisted, image-guided navigation

CPT® code	CPT® description:	2025 Total non-facility RVUs	2025 MPFS non-facility payment	2025 Total facility RVUs	2025 MPFS facility payment	MPPI**
+31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (list separately in addition to code for primary procedures)	30.24	$978	2.82	$91	0

+ indicates code is an add-on code

Bronchoscopy with biopsy(s) of additional lobe

CPT® code	CPT® description:	2025 Total non-facility RVUs	2025 MPFS non-facility payment	2025 Total facility RVUs	2025 MPFS facility payment	MPPI**
+31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	1.92	$62	1.42	$46	0
+31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	2.41	$78	1.85	$60	0

+ indicates code is an add-on code

**MPPI – Multiple Procedure Payment Indicator

- No payment adjustment rules for multiple procedures apply. If the procedure is reported on the same day as another procedure, the procedure is paid at the lower of the actual charge or the fee schedule amount for the procedure.
- Standard payment rules for multiple procedures apply. If the procedure is reported on the same day as another procedure with a numeric designation of 1, 2 or 3, rank each procedure by the fee schedule amount and take the appropriate reduction: Highest valued procedure: 100%, Second, third, fourth, and fifth valued procedures: 50% for each procedure beyond the fifth.
- Special rules for multiple endoscopic procedures apply when the procedure is performed with another endoscopic procedure in the same family (i.e., another endoscopy that has the same base procedure).

Facility coding and billing information

Listed below are commonly used procedure codes during bronchoscopy where navigation may be performed. Providers may choose to perform multiple procedures during the same encounter. When this occurs, the payment may be subject to packing rules or a complexity-adjusted payment.

Bronchoscopy with biopsy in a hospital outpatient department

CPT® code	CPT® description:	Status indicator	APC	2025 National payment rate
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)	J1	5153	$1,724
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings	J1	5153	$1,724
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage	J1	5153	$1,724
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites	J1	5153	$1,724
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers	J1	5155	$6,922
+31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with computer-assisted, image-guided navigation (list separately in addition to code for primary procedures)	N	N/A	Packaged
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe	J1	5154	$3,687
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s) trachea, main stem and/or lobar bronchus	J1	5154	$3,687
+31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	N	N/A	Packaged
+31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	N	N/A	Packaged

+ indicates code is an add-on code

CMS-1786-FC, Addenda A, B, J

Facility coding and billing information

Select 2025 hospital outpatient complexity adjustment pairings

Primary CPT® code	Primary procedure short descriptor	Secondary CPT® code	Secondary procedure short descriptor	Complexity adjusted APC assignment	Complexity adjusted APC payment rate
31629	Bronchoscopy/needle bx each	31628	Bronchoscopy/lung bx each	5155	$6,922
31629	Bronchoscopy/needle bx each	31629	Bronchoscopy/needle bx each	5155	$6,922
31629	Bronchoscopy/needle bx each	31641	Bronchoscopy treat blockage	5155	$6,922
31629	Bronchoscopy/needle bx each	31653	Bronchoscopy EBUS sampling 3/> node	5155	$6,922
31653	Bronchoscopy EBUS sampling 3/> node	31628	Bronchoscopy/lung bx each	5155	$6,922
31653	Bronchoscopy EBUS sampling 3/> node	31640	Bronchoscopy w/tumor excise	5155	$6,922
31653	Bronchoscopy EBUS sampling 3/> node	31641	Bronchoscopy treat blockage	5155	$6,922
31622	Dx bronchoscope/ wash	31627	Navigational bronchoscopy	5154	$3,687
31624	Dx bronchoscope/ lavage	31627	Navigational bronchoscopy	5154	$3,687
31624	Dx bronchoscope/ lavage	31654	Bronch EBUS ivntj perph lesion	5154	$3,687
31625	Bronchoscopy w/biopsy(s)	31623	Dx bronchoscope/brush	5154	$3,687
31625	Bronchoscopy w/biopsy(s)	31624	Dx bronchoscope/lavage	5154	$3,687
31625	Bronchoscopy w/biopsy(s)	31627	Navigational bronchoscopy	5154	$3,687
31625	Bronchoscopy w/biopsy(s)	31635	Bronchoscopy with fb removal	5154	$3,687
31625	Bronchoscopy w/biopsy(s)	31645	Brnchsc with ther aspir 1st	5154	$3,687
31625	Bronchoscopy w/biopsy(s)	31654	Bronch EBUS ivntj perph lesion	5154	$3,687

CMS-1786-FC, Addenda A, J

CMS transitional pass-through payment status (TPT)

TPT is a program administered by CMS that provides incremental payment in the hospital outpatient setting for qualifying categories of technologies.[4] Once approved by CMS, the TPT lasts for three years and allows CMS collects hospital claims information to calculate future hospital outpatient APC payment rates.

In the CY 2025 Final Hospital Outpatient Prospective Payment System Rule, CMS approved a TPT application associated with single-use pulmonary endoscopes.[5] As a result, effective January 1, 2024, CMS created a new device category to identify technologies that qualify for this specific TPT:

C1601, Endoscope, single-use (i.e., disposable), pulmonary, imaging/illumination device (insertable).

Further, CMS identified various primary procedures to which C1601 is applicable, including[6]:

CPT® code	Procedure description	APC	2025 National payment rate	Device offset
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure)	5153	$1,724	$8.57
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with brushing or protected brushings	5153	$1,724	$6.47
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial alveolar lavage	5153	$1,724	$2.91
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites	5153	$1,724	$14.88
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers	5155	$6,922	$652.77
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe	5154	$3,687	$36.04
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s) trachea, main stem and/or lobar bronchus	5154	$3,687	$44.96

CMS has stated that TPT is not necessarily specific to one technology. Instead, CMS creates device categories (e.g., C1601) that allow any technology that is appropriately described by that device category to bill for TPT during the three-year duration. It is advised that each provider confirms the use of any code, including C1601, with the provider's billing advisor or payer.

TPT applies to traditional Fee-For-Service Medicare patients. Please check with other payers to determine if TPT applies. For Medicare, the TPT payment is calculated on a claim-by-claim basis, and is based on the following factors:

- The primary procedure that is performed with a device described by C1601;
- The device offset associated with that procedure;
- The charges established by the hospital for C1601 in its chargemaster, and
- The hospital's cost-to-charge ratio (CCR) for the revenue center "Implantable Devices Charged to Patients" or "Medical Supplies" (if the former is not available)

[4]https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-newtechnology-ambulatory-payment-classification-apc

[5]https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices/cms-1786-fc

[6]https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2023-transmittals/r12421cp

TPT examples

Example 1:

Charges for device category C1601: $7,500

Implantable devices charged to patients CCR: 0.2689

Primary procedure CPT code: 31628

	Element	Calculation	Amount
Hospital charges for C1601	A		$7,500
Hospital implantable devices CCR	B		x 0.2689
Reported cost of C1601	C	A x B	$2,017
Device-related offset of CPT code 31628	D		- $36
Incremental TPT payment	E	C – D	$1,981
APC assignment for CPT code 31628 (APC 5154)	F		+ $3,687
Total APC+ TPT payment	G	E + F	$5,668

Example 2 (Complexity adjusted):

Charges for device category C1601:..... $7,500

Implantable devices charged to patients CCR: 0.2689

Primary and secondary procedure CPT codes: .....31629 + 31629

	Element	Calculation	Amount
Hospital charges for C1601	A		$7,500
Hospital implantable devices CCR	B		x 0.2689
Reported cost of C1601	C	A x B	$2,017
Device-related offset of CPT code 31629	D		- $45
Incremental TPT payment	E	C – D	$1,972
Complexity adjusted APC assignment (APC 5155)	F		+ $6,922
Total APC+ TPT payment	G	E + F	$8,894

(for illustrative purposes only)

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The provider is solely responsible for all clinical decisions, patient management, use of appropriate codes, claims submission, billing, and determining medical necessity in compliance with all applicable laws, regulations, rules, payor policies and manuals.

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