DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, 419, 424, 485, 488, and 489

Office of the Secretary

45 CFR Part 180

[CMS–1786–FC]

RIN 0938–AV09

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Hospital Outpatient Departments, Community Mental Health Centers, Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for calendar year 2024 based on our continuing experience with these systems. In this final rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. Also, this final rule updates and refines the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program. In this final rule, we are also establishing a payment for certain intensive outpatient services under Medicare, beginning January 1, 2024. In addition, this final rule updates and refines requirements for hospitals to make public their standard charge information and enforcement of hospital price transparency. We are finalizing changes to the community mental health center (CMHC) Conditions of Participation (CoPs) to provide requirements for furnishing intensive outpatient (IOP) services, and we are finalizing the proposed personnel qualifications for mental health counselors (MHCs) and marriage and family therapists (MFTs). Additionally, we are finalizing the removal of discussion of the inpatient prospective payment system (IPPS) Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the fiscal year (FY) 2025 rulemaking. Finally, we are finalizing a technical correction to the Rural Emergency Hospital (REH) CoPs under the standard for the designation and certification of REHs.

DATES:

Effective date: The provisions of this rule are effective January 1, 2024.

Comment period: To be assured consideration, comments must be received at one of the addresses provided below, by January 1, 2024.

ADDRESSES: In commenting, please refer to file code CMS–1786–FC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1786–FC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1786–FC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Au'Sha Washington, *AushaWashington@cms.hhs.gov* or 410–786–3736.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov.*

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at *marsha.hertzberg@cms.hhs.gov.*

Biosimilars Packaging Exception, contact Gil Ngan via email at *gil.ngan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov.*

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov.*

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov.*

Community Mental Health Centers (CMHC) Conditions of Participation, contact Mary Rossi-Coajou via email at *Mary.RossiCoajou@cms.hhs.gov* or Cara Meyer via email at *Cara.Meyer@cms.hhs.gov*.

Composite APCs (Multiple Imaging and Mental Health), via email at Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov.*

COVID–19 Final Rules, contact Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email *Kimberly.Go@cms.hhs.gov.*

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Abby Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Hospital Price Transparency (HPT), contact Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov*.

Inpatient Prospective Payment System (IPPS) Medicare Code Editor, contact Mady Hue via email at *Marilu.Hue@cms.hhs.gov*.

Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes, contact Emily Yoder via email at *Emily.Yoder@cms.hhs.gov.*

Method to Control Unnecessary Increases in the Volume of Clinic Visit

− $217.36)/$1,422.51) × 100 = 516.67 percent). Therefore, we stated that we believe CERAMENT® G meets the third cost significance requirement.

We invited public comment on whether the CERAMENT® G meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive public comments regarding whether CERAMENT® G meets the cost criteria at § 419.66(d)(1) through (3). Based on the information we have received, we have determined that CERAMENT® G meets the cost criterion for device pass-through payment status.

After consideration of the public comments we received, and our review of the device pass-through application, we have determined that CERAMENT® G meets the requirements for device pass-through status described at § 419.66. As stated previously, devices that are granted an FDA Breakthrough Device designation and have marketing authorization for the indication covered by the Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2)(i) for the purposes of determining device pass-through payment status but must meet the other criteria for device pass-through status. We believe CERAMENT® G meets the criteria at § 419.66, and therefore, effective beginning January 1, 2024, we are finalizing approval for device pass-through payment status for CERAMENT® G under the alternative pathway for devices that have an FDA Breakthrough Device designation and have received FDA marketing authorization for the indication covered by the Breakthrough Device designation.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScope™ 5 Broncho HD

Ambu Inc. submitted an application for a new device category for transitional pass- through payment status for the Ambu® aScope™ 5 Broncho HD for CY 2024. Per the applicant, the Ambu® aScope™ 5 Broncho HD is one component of the Ambu® aScope™ 5 Broncho HD System which consists of: (1) the Ambu® aScope™ 5 Broncho HD (5.0/2.2 or 5.6/2.8), a sterile, single-use, disposable flexible/rigid bronchoscope; and (2) Ambu® aBox™ 2, a compatible, reusable display unit. The applicant is only seeking a new device category for transitional pass through payment status for the Ambu® aScope™ 5 Broncho HD component.

Per the applicant, the Ambu® aScope™ 5 Broncho HD, consists of: (1) a handle, to hold the scope (designed for left or right hand); (2) a control lever, to move the distal tip up or down in a single plane; (3) a working channel and working channel port, for instillation of fluids and insertion of endotherapy instruments; (4) a biopsy valve, to be attached to the working channel port, for insertion of endotherapy instruments or attachment of a syringe; (5) a suction connector, for connection of suction tubing; (6) a suction button, to activate suction when pressed; (7) endoscope buttons 1 and 2 (depending on settings in display unit, the two remote switches allow for direct activation on handle of four different functionalities such as image and video capturing, initiate advanced red contrast (ARC), and zoom); (8) a rotation control ring, for rotation of the insertion cord during procedure; (9) a tube connection, for fixation of tubes with standard connector during procedure; (10) an insertion cord and insertion portion, flexible airway insertion cord; (11) bending section, maneuverable part; (12) distal tip, which contains the camera, light source (two light-emitting diodes (LEDs)), and the working channel exit; (13) display unit connector, to connect to the port on the Ambu® aBox™ 2 display unit; (14) a cable, to transmit the image signal to the Ambu® aBox™ 2 display unit; (15) a protective handle cover, to protect the control lever during transport and storage; (16) a protective pipe, to protect the insertion cord during transport and storage; and (17) an introducer, to facilitate introduction of luer lock syringes.

The applicant stated that the Ambu® aScope™ 5 Broncho HD is an imaging/illumination bronchoscope device that uses an integrated camera module and built-in dual LED illumination to provide access to, and imaging of, the lungs for diagnostic and therapeutic purposes for patients with pulmonary pathology. The device is intended for endoscopy and endoscopic surgery within the lungs, also known as bronchoscopy. According to the applicant, the Ambu® aScope™ 5 Broncho HD was designed to perform a wide array of diagnostic and interventional pulmonology procedures. The applicant noted that the Ambu® aScope™ 5 Broncho HD is a single-use bronchoscope designed to be used with the Ambu® aBox™ 2 display unit, endotherapy instruments and other ancillary equipment for bronchoscopic procedures, and examination within the airways and the tracheobronchial tree. It is intended to provide visualization via the compatible display unit, the Ambu® aBox™ 2, and to allow passage of endotherapy instruments via its working channel.

Per the applicant, the Ambu® aScope™ 5 Broncho HD bronchoscope is inserted into the patient airway through either the mouth, nose, or via a tracheostomy, if present. The applicant explained that when the Ambu® aScope™ 5 Broncho HD bronchoscope has reached the correct position, endotherapy instruments can be inserted into the working channel system of the bronchoscope. Per the applicant, an introducer supplied with the bronchoscope can be attached to the working channel port via a luer lock adaptor while the bronchoscope is in use. The applicant noted that the suction system may be used to remove blood, saliva, and mucus from the airway. The applicant indicated that a bronchoscope operator monitors the field of view via the integrated camera of the Ambu® aScope™ 5 Broncho HD bronchoscope and the procedure is finished when the device is pulled out completely.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on July 25, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ 5 Broncho HD as a device to be used for endoscopic procedures and examination within the airways and tracheobronchial tree. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1).

We did not receive public comments regarding whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1). We received the application for a new device category for transitional pass-through payment status for Ambu® aScope™ 5 Broncho HD on February 28, 2023, which is within 3 years of July 25, 2022, the date of FDA 510(k) approval to market the Ambu® aScope™ 5 Broncho HD, and as such we have concluded that the Ambu® aScope™ 5 Broncho HD meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), according to the

applicant, the Ambu® aScope™ 5 Broncho HD is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted as required by § 4189.66(b)(3).

We invited public comment on whether the Ambu® aScope ™ 5 Broncho HD meets the criterion at § 419.66(b)(3).

We did not receive any comments on whether the Ambu® aScope ™ 5 Broncho HD meets the eligibility criteria at § 419.66(b)(3). Based on the information we have received and our review of the application, we agree with the applicant that Ambu® aScope ™ 5 Broncho HD is integral to the service provided, used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted. Therefore, we have determined that Ambu® aScope ™ 5 Broncho HD meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether the Ambu® aScope ™ 5 Broncho HD is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the Ambu® aScope ™ 5 Broncho HD is a supply or material furnished incident to a service.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the exclusion criterion at § 419.66(b)(4).

Comment: The applicant asserted that the Ambu® aScope™ 5 Broncho HD meets the eligibility requirements at § 419.66(b)(4). The applicant clarified that the device is not equipment, an instrument, apparatus, implement, or item for which depreciation and financing are recovered. The applicant indicated that the device is not a material or supply furnished incident to a service. The applicant stated that the device is purely an operating cost and is not subject to capitalization or a depreciation schedule.

Response: We appreciate the applicant's input. Based on the information we have received and our review of the application, we agree with the applicant that the Ambu® aScope™ 5 Broncho HD meets the device eligibility requirements of § 419.66(b)(4) because it is not a piece of equipment, instrument, apparatus, implement, or item for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service. Therefore, we have determined that the Ambu® aScope™ 5 Broncho HD meets the eligibility criterion at § 419.66 (b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described the Ambu® aScope™ 5 Broncho HD as a single-use, disposable, digital flexible/rigid bronchoscope that is used in pulmonary procedures (bronchoscopy) to diagnose and treat conditions of the lungs, including tumors or bronchial cancer, airway blockage (obstruction), narrowed areas in airways (strictures), inflammation, and infections such as tuberculosis (TB), pneumonia, fungal or parasitic lung infections, interstitial pulmonary disease, causes of persistent cough, causes of coughing up blood, spots seen on chest X-rays, and vocal cord paralysis. The applicant claimed that the Ambu® aScope™ 5 Broncho HD is different from other endoscopes because it is a single-use endoscope indicated for use in the respiratory system, the device records snapshots or video of images, and the device is temporarily inserted into the patient airway to diagnose and treat lung problems. According to the applicant, there are two possible existing pass-through device categories, represented by the following codes: C1748 (Endoscope, single-use (that is, disposable), upper gastrointestinal tract (GI), imaging/illumination device (insertable)); and C1747 (Endoscope, single-use (that is, disposable), urinary tract, imaging/illumination device (insertable)). The applicant noted that while these two codes are for single-use endoscopic devices, they are only appropriate for GI and urinary tract imaging, respectively. Therefore, the applicant asserted that these two codes would not apply to a single-use, disposable, bronchoscope for use in pulmonary procedures. We noted that while C1748 and C1747 are intended to be used in different anatomical areas of the patient, the codes for both device categories describe devices that are single use and have imaging capabilities.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device category criterion at § 419.66(c)(1).

Comment: The applicant reiterated that the device is not appropriately described by any existing device categories. The applicant noted that although HCPCS codes C1747 and C1748 do describe single-use endoscopes and have imaging capabilities, they are intended to be used in different anatomical areas, specifically the urinary tract and the upper GI tract, respectively. The applicant asserted that the device is used in pulmonary procedures and meets the device category criterion. Another commenter referenced an FDA guidance [21] on the 510(k) Program issued on July 28, 2014, to support the applicant's assertion by stating that the device was cleared for marketing under 21 CFR 874.4680, and therefore the device cannot be legally labeled for use or otherwise promoted for GI/urology use.

Response: We appreciate the applicant and commenter's input. Based on the information we have received and our review of the application, we agree there is no existing pass-through payment category that appropriately describes the Ambu® aScope™ 5 Broncho HD because no current or previously in effect category describes a single-use endoscope indicated for use in the respiratory system. Based on this information, we have determined that the Ambu® aScope™ 5 Broncho HD meets the eligibility criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies by: (1) eliminating complex cleaning/reprocessing procedures, (2) reducing microbial transmission and infection since it is single-use, (3) eliminating the need for continuous training of reprocessing staff, (4) minimizing the risk of patient

[21] FDA Guidance July 28, 2014. ''The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notification [510(k)]: Guidance for Industry and Food and Drug Administration Staff''.

cross-contamination, (5) assuring that a sterilized scope will be used each time, and (6) assuring that there will be no biofilm from endoscope channels. The applicant provided four articles, an FDA guidance letter, and an FDA safety notice specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates complex cleaning/reprocessing procedures because it is a single-use device, the applicant referenced an FDA Reprocessing Final Guidance document [22] issued March 17, 2015. This FDA document provides guidance to medical device manufacturers on the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended. The guidance document is limited to reusable medical devices and single-use medical devices that are initially supplied as non-sterile to the user and require the user to process the device prior to its use. In this guidance document, the FDA identifies a subset of reusable medical devices (including bronchoscopes and accessories) that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed and indicates design features which may pose a challenge to adequate reprocessing for arthroscopes, laparoscopic instruments, and electrosurgical instruments, and their respective accessories. However, the FDA guidance does not mention sterile, single-use medical devices in this document.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD reduces microbial transmission and infection because it is single use, the applicant referenced an FDA safety notice [23] issued on September 17, 2015 (2015 FDA safety notice). The FDA notice discussed the findings of an investigation into infections associated with reprocessed reusable medical devices, including an analysis of Medical Device Reports (MDRs) submitted to FDA from manufacturers and health care facilities. The notice provided that between January 2010 and June 2015, FDA received 109 MDRs concerning infections or device contamination associated with flexible bronchoscopes. However, FDA noted that, when compared to the number of bronchoscopy procedures performed in the U.S. each year, this is considered a small number of MDRs. In 2014, FDA received 50 MDRs that mentioned infections or device contamination associated with reprocessed flexible bronchoscopes, which prompted additional investigation of this issue. FDA indicated that a small number of the reported infections were from persistent device contamination despite following the manufacturer's reprocessing instructions, however, most of the infections were the result of the failure to meticulously follow manufacturer instructions for reprocessing, or the continued use of devices despite integrity, maintenance, and mechanical issues. FDA provided additional recommendations for health care facilities and staff that reprocess flexible bronchoscopes, and for patients considering bronchoscopy procedures, but did not reference single-use bronchoscopes in the notice.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates the need for continuous training of reprocessing staff, the applicant referenced a study by Châteauvieux et al.,[24] which assessed the organizational and economic impacts of the introduction of a single-use flexible bronchoscope (FB) (Ambu® aScope™, versions 2 and 3) in comparison with a reusable FB (Pentax®) at the hospital level. The study took place between May 2016 and October 2016 in the Georges Pompidou European Hospital, an 800-bed university hospital in France. Châteauvieux et al. noted that the introduction of single-use FBs led to a more simplified process, less stress for medical and paramedical staff in emergency situations, teaching benefits, and easier management of transport, in comparison with reusable FBs. However, the authors recommended limiting the use of single use FBs to specific situations, and to prioritize the use of reusable devices for most of the bronchoscopies for cost savings.

The applicant referred to a meta study by Barron and Kennedy [25] to support its claim that the use of Ambu® aScope™ 5 Broncho HD minimizes the risk of patient cross-contamination, ensuring that health care providers have taken optimal steps to safeguard their patients. Barron and Kennedy summarized the major advantages of single-use FBs over the standard reusable FBs in clinical scenarios. The authors noted that single-use FBs offer a safer alternative to standard reusable FBs in specific scenarios where reduced risk of cross infection was critical in the immunocompromised patient and in rare cases of prior contamination due to transmissible spongiform encephalopathies.

The applicant referred to a self-sponsored study [26] by Ofstead et al.[27] in 2019, in support of its claim that the use of the Ambu® aScope™ 5 Broncho HD ensures a sterilized scope is available for each procedure while reusable endoscopes may not be sterile even if manufacturers' cleaning protocols are followed. The study first referenced Ofstead et al.'s 2017 [28] evaluation of the effectiveness of bronchoscope processing in three large hospitals where every bronchoscope had visible defects, protein was detected on 100 percent of high-level disinfected bronchoscopes, and bacteria or mold was found on 58 percent of the patient-ready bronchoscopes. Then, in 2019, Ofstead et al. conducted a study to determine the time and cost of acquiring, maintaining, and reprocessing bronchoscopes in four hospitals (two in the Midwest and two in the West Coast). Three hospitals had obtained single-use Ambu® bronchoscopes (2018, version unspecified) for procedures done in certain departments, after hours, or in emergency situations. Per Ofstead et al.

[22] FDA Guidance March 17, 2015. ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff''. *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf.*

[23] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[24] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[25] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[26] Ofstead et al. acknowledged that this study was supported by an unrestricted research grant from Ambu Inc. The study sponsor did not participate in designing the study, identifying sites, collecting data, compiling results, interpreting the findings, or writing this article.

[27] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing bronchoscope quality and cost: results of a real-world study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[28] Ofstead C.L., Quick M.R., Wetzler H.P., et al. (2018) Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest, 154*(5):1024–34.

(2019), the cost for procedures with reusable bronchoscopes ($281 to $803) were comparable or higher than the cost of single-use bronchoscopes ($220 to $315), due to acquisition and maintenance of large inventories of bronchoscopes to ensure real-time availability for various hospital departments. Ofstead et al. (2019) suggested the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities. Ofstead et al. (2019) summarized the steps that can be taken to reduce risks related to bronchoscope contamination and to focus on implementing quality management systems to improve personnel competence, bronchoscope inventory management, maintenance, reprocessing effectiveness, and storage. In addition to following manufacturer's steps for reprocessing the devices, Ofstead et al. (2019) suggest the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities, which are currently available in the list of recommendations.

The applicant referenced a review article by Kovaleva et al.[29] in support of its claim that the Ambu® aScope™ 5 Broncho HD's single-use feature is free of biofilm from endoscope channels since routine cleaning procedures do not remove biofilm reliably from endoscope channels. This review presents an overview of the infections and cross-contaminations related to flexible gastrointestinal endoscopy and bronchoscopy and illustrates the impact of biofilm on endoscope reprocessing and post-endoscopic infection. Kovaleva et al. noted that the use of antibiofilm-oxidizing agents with an antimicrobial coating inside washer disinfectors could reduce biofilm build-up inside endoscopes and automated endoscope re-processors and decrease the risk of transmitting infections.[30] Per Kovaleva et al. while sterilization can be helpful to destroy microorganisms within biofilms, ethylene oxide sterilization may fail in the presence of organic debris after an inadequate cleaning procedure before reprocessing of flexible endoscopes. There was no mention of single-use bronchoscopes in the study.

The applicant cited a self-sponsored, laboratory study by Kurman et al.,[31] in general support of its application. Kurman et al. evaluated and assessed four different manufacturers' single-use flexible bronchoscopes (SFB), including the nominated device and its prior model, against their reusable flexible bronchoscopes (RFB) on a cadaver (that is, corpse) model, benchtop fixturing, and an artificial plastic lung model. The study compared the Ambu® aScope™ 5 Broncho HD with four devices: (1) Olympus H-SteriScope; (2) Verathon BFLEX; (3) Boston Scientific Exalt-B; and (4) Ambu® aScope™ 4 Broncho (the prior model of the nominated device). The study concluded that the Ambu® aScope™ 5 Broncho HD has the highest overall performance, the highest overall rating for sampling, and highest maneuverability in difficult segmental airways among the comparator devices.

The applicant indicated that the Ambu® aScope™ 5 Broncho HD differs from these comparator devices as it is the only device that is compatible with argon gas plasma coagulation, cryotherapy, and laser, with an HD (1200x800) chip, has more degrees of articulation with tools, and provides image and video capture from the scope handle with multiple programmable functions including capture photo, start/end video, enable zoom, and initiate ARC. In addition, the applicant stated that the nominated device is superior to its earlier legally marketed device in terms of maneuverability into difficult segmental airways, overall performance, and overall sampling assessment. The applicant asserted that the nominated device differs from the predicate device due to a rotation mechanism on the handle and its superior articulation, which allow for more complicated procedures to be performed such as cryotherapy and coagulation. The applicant stated that the nominated device is equipped with an HD image chip and increased depth-of-field and field-of-view, which allow interventional pulmonologists to perform inspections, biopsies, and debulking. The applicant also stated that the nominated device's programmable buttons allow for superior documentation than the earlier bronchoscope device.

We noted that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed. The FDA 510(k) summary indicated that both devices share similar technological characteristics including the optical system, bending section, diameter of insertion cord and distal end, and insertion portion length. Furthermore, the 510(k) summary indicated that both have the same technical characteristics, which include a maneuverable tip controlled by the user, flexible insertion cord, camera and a LED light source at the distal tip. Both are sterilized by ethylene oxide, are single-use devices, and have the ability to aspirate and collect samples in bronchoalveolar lavage and bronchial wash procedures.

We noted that in its application, the applicant provided a comparison of certain devices or device categories that it believed are most closely related or similar to the Ambu® aScope™ 5 Broncho HD. The applicant identified six reusable devices that it believed are most closely related: (1) Olympus Evis Exera Iii Bronchovideoscope Bf-h190; (2) Pentax EB–J10 Video Bronchoscope; (3) Fujifilm EB–580S Video Bronchoscope; (4) Olympus BF–Q190; (5) Olympus BF–1TH190; and (6) Olympus BF–XT190. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the Ambu® aScope™ 5 Broncho HD is used. The applicant stated that the Ambu® aScope™ 5 Broncho HD's single-use feature is unique among the comparators. According to the applicant, the single-use feature eliminates bronchoscope reprocessing. The applicant further submitted several articles reporting results on the prevalence of infection due to incomplete or inadequate processing for reusable bronchoscopes, which we summarize as follows. An article by Shimizu et al.[32] concluded that patients with larger lesions, endobronchial lesions, histology of small-cell lung cancer, and advanced-disease stage tended to develop pulmonary infectious complications more often than other patients. A 2020 systematic literature review and meta-analysis by Travis et al.[33] reported an estimated average reusable FB cross-contamination rate of 8.69 percent ± 1.86 (standard division [SD]) (95 percent confidence interval [CI]: 5.06–12.33 percent) among eight

[29] Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. *Clinical microbiology reviews, 26*(2), 231–254. *https://doi.org/10.1128/CMR.00085-12.*

[30] *Ibid.*

[31] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[32] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[33] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of infection prevention,* 17571774231158203.

studies from the U.S. and four European countries. Travis et al.[34] attributed the infection rate to the differences in the study design and sampling methods, geography, low number of data points, clinical settings, and an aversion towards publishing negative findings among the eight studies. Furthermore, the applicant submitted a 2019 systematic review and cost-effective analysis by Mouritsen et al.,[35] which reported an average 2.8 percent cross-contamination rate from reusable, flexible bronchoscopes among 16 studies from the United Kingdom, U.S., France, Spain, Australia, and Taiwan. Mouristen et al. identified that the single-use flexible bronchoscopes were cost effective and associated with a reduction of infection risk of approximately 1.71–4.07 percent compared with reusable flexible bronchoscopes. Lastly, the applicant again cited the meta study by Barron and Kennedy [36] referencing the findings from Ofstead et al.,[37] the review by Mouristen et al., and the Emergency Care Research Institute's (ECRI's) report.[38] Of note, ECRI highlighted the recontamination of flexible endoscopes due to mishandling or improper storage as one of the top 10 health technology hazards.

Based on the evidence submitted with the application, we noted the following concerns: We noted concern about whether the Ambu® aScope™ 5 Broncho HD can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Four of the studies the applicant submitted, Châteauvieux et al.,[39] Barron and Kennedy, Kurman et al., and Ofstead et al., investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. In addition, we noted that the studies provided also did not compare the nominated device to an appropriate comparator such as a single-use bronchoscope from a different manufacturer or a standard reusable bronchoscope, in a clinical setting. In addition, we noted that the applicant's self-sponsored study by Kurman, et al. was conducted in the laboratory (that is, on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

Furthermore, we noted that the Châteauvieux et al.[40] and Barron and Kennedy [41] studies suggested limiting the use of single-use bronchoscope device to specific situations (that is, after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting. We believed that further investigation with comparators in these specified cases would be particularly helpful to determine whether the device demonstrates a substantial clinical improvement over currently available treatment options in the clinical setting where it is most likely to be used.

We noted concern that the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable bronchoscope procedures, but do not directly show any clinical improvement that results from the use of the Ambu® aScope™ 5 Broncho HD. We noted that Shimizu et al.,[42] Travis et al.,[43] Barron and Kennedy,[44] and Ofstead et al.[45] provided information about the risks associated with reprocessing reusable devices and reported mixed results.

We also noted that the 2015 FDA safety notice [46] provided preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes, but did not discuss or recommend the use of disposable, single-use devices in the notice. Furthermore, we noted the following concerns about studies on the prevalence of infection due to incomplete/inadequate reprocessing of reusable bronchoscopes. The studies authored by Châteauvieux et al.,[47] Shimizu et al.,[48] Travis et al.,[49] and Mouritsen et al.[50] have small sample sizes. Furthermore, the Barron and Kennedy,[51] Travis et al.,[52] and Mouritsen et al.[53] studies used different

[34] *Ibid.*

[35] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[36] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[37] Ofstead C.L., Quick M.R., Wetzler H.P., et al. (2018) Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. *Chest, 154*(5):1024–34.

[38] ECRI. Top 10 health technology hazards. Executive brief. Pennsylvania: ECRI Institute, Health devices; 2019. p. 2019.

[39] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[40] *Ibid.*

[41] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[42] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[43] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of infection prevention,* 17571774231158203.

[44] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[45] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing bronchoscope quality and cost: results of a real-world study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[46] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[47] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[48] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[49] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention,* 17571774231158203.

[50] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[51] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[52] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention,* 17571774231158203.

[53] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic

Continued

study designs and sampling methodologies or were performed in various clinical settings other than outpatient, which may affect the quality and reliability of the data provided in support of the applicant's assertions. We did not believe that we had sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the nominated device. We sought comments on the prevalence of infection due to incomplete/inadequate processing for bronchoscopes in the U.S. and whether single-use bronchoscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

The applicant provided evidence which seemed to rely on indirect inferences from other sources of data. We questioned the relevance of the 2015 FDA safety notice [54] to the nominated device because as stated above, the guidance applies to reprocessed flexible bronchoscopes broadly, but not to disposable, single-use devices comparable to the nominated device. We expressed concern that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection. We expressed concern that the applicant provided studies with small sample sizes and other limitations, as described above, as their only support. We noted that the applicant provided background information on the established reprocessing guidelines [55] for reusable devices; however, the existence of reprocessing guidelines does not provide evidence on the prevalence of infection rates, establish a relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be a substantial clinical improvement over currently available treatments.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

Comment: The applicant and several commenters responded to our concern about whether the Ambu® aScopeTM 5 Broncho HD could be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement and that four of the studies the applicant submitted, Châteauvieux et al., Barron and Kennedy, Kurman et al.,[56] and Ofstead et al., investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. The applicant and commenters provided feedback that Ambu® aScope™ 5 Broncho HD improves clinical applications and reduces cross-contamination compared to other single-use and reusable bronchoscopes, including its predicate device. Several commenters stated that the device can perform advanced bronchoscopy procedures, without concern for contamination, infection, and scope damage. One commenter stated that they have witnessed the usage of this bronchoscope for advanced procedures without incident, noting that it is the preferred device in their clinical practice for valve placement, rigid bronchoscopy, and all cases outside of the endoscopy suite. Another commenter noted that reusable bronchoscopes have a complex design with variable disinfection/sterilization requirements which leads to issues with reprocessing. Multiple commenters stated that single-use bronchoscopes create an assurance that a sterilized scope will be used each time, reduce the risk of patient cross-contamination in the ICUs, and allow improved patient access and room turnover compared with reusable scopes. One commenter asserted that the nominated device is superior to other devices in specific patient populations needing interventional pulmonology procedures.

Commenters cited personal experience with Ambu® aScope™ 5 Broncho HD, asserting that transitioning to the nominated device several months ago has eliminated iatrogenic bronchoscopy-related transmission of infection in their health care facility and Ambu® aScope™ 5 Broncho HD has directly led to clinical improvement in cases of endobronchial valve insertion in their facility, as more patients can be treated with endobronchial valve insertion for bronchoscopic lung volume reduction. The applicant provided that after being commercially available for one year in Europe, the USA, Canada, Australia, New Zealand, and Japan, they observed that more than 80 percent of users have adopted the nominated device into their bronchoscopy suites for advanced procedures, including but not limited to tumor debulking, endobronchial valve placement, cryobiopsy, as well as endobronchial and transbronchial biopsies, which single-use bronchoscopes were previously unable to perform. The applicant reiterated that the device is the only single-use flexible bronchoscopy (FB) capable of performing advanced bronchoscopy as it has superior bending angles, an HD imaging chip, and is compatible with argon gas plasma coagulation, cryotherapy, and laser. The applicant also asserted that early clinical feedback suggests that the device is a viable alternative to reusable bronchoscopes due to its superior angulation range and flexibility. Further, the applicant clarified that the Kurman et al.[57] study did provide data on the nominated device, including table providing a side-by-side comparison of the technical specs of the Ambu® aScope™ 5 Broncho HD and its comparators which showed that the nominated device had better flexion and extension without tools compared to the reusable scope, the nominated device had the most degrees of flexion and extension with all accessory tools compared to other single-use scopes and the reusable scope, the nominated the device was able to reach the same anatomical location with biopsy forceps in the right-upper lobe segment, and the nominated device rated similar to the reusable scope and better than the other single-use scopes in image sharpness and near and far field resolutions.

Finally, the applicant asserted that while there are similarities between Ambu® aScope™ 5 Broncho HD and the predicate devices, the Ambu® aScope™ 5 Broncho HD can be distinguished from the predicate devices because its technical characteristics, such as a rotation mechanism on the handle and superior articulation, which allow it to perform more complex bronchoscopy procedures, are unique to the Ambu® aScope™ 5 Broncho HD.

Response: We appreciate the commenters' examples supporting the superiority of the Ambu® aScope™ 5 Broncho HD. In addition, we appreciate the clarification on the Kurman et al.[58]

review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[54] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[55] FDA Guidance March 17, 2015 ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff''.

[56] Kurman, J., Wagh, A., Benn, B., & Islam, S. (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[57] *Ibid.*

[58] *Ibid.*

study along with the table providing a side-by-side comparison of the technical specs of the Ambu® aScope™ 5 Broncho HD and its comparators. After reviewing the information provided in the public comment and clarifications from the applicant on the Kurman et al.[59] study that directly compare the nominated device with other single-use scopes, we agree with the commenters' and the applicant's statements that the device can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement.

Comment: In response to our concern that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed, and the FDA 510(k) summary indicated that both devices have the same technical characteristics, the applicant along with a few commenters expressed their belief that the FDA 510K term ''substantially equivalent'' does not imply the device is the same as its predicate device. Rather, the applicant asserted that the 510(k) term ''substantially equivalent'' indicates that a nominated device is as safe and effective as its predicate device. One commenter noted that as defined in 21 CFR part 807,[60] every 510(k)-cleared medical device has been found substantially equivalent to one or more predicate devices. One commenter suggested that the regulatory substantial equivalence cannot be used to conclude the inability to demonstrate substantial clinical improvement in the context of CFR 419.66(c)(2).

Response: We appreciate the comments regarding the FDA 510K term ''substantially equivalent'' and the reference to 21 CFR part 807.[61] We agree that FDA determination of substantial equivalence cannot alone be used to conclude that a device cannot to demonstrate substantial clinical improvement as required by the regulation at 42 CFR 419.66(c)(2). However, we note that the FDA 510(k) summary provided by the applicant indicated that both nominated and predicate devices share similar technological characteristics such as optical system, bending section, diameter of insertion cord and distal end, and insertion portion length. We expressed concern in the proposed rule regarding the language in the FDA 510(k) summary because we could not determine, based on the information available to us at the time, whether the Ambu® aScope™ 5 Broncho HD could be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Neither could we determine exactly how the nominated device is superior to its earlier legally marketed device, as per the applicant's assertion. As noted above, after reviewing the information provided in the public comment, particularly the Kurman et al.[62] study, we agree with the commenters' and the applicant's statements that the device can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement.

Comment: In response to the concern that the applicant's self-sponsored study by Kurman et al.[63] may not be sufficient to show improved clinical outcomes because it was conducted in the laboratory (that is, on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting, the applicant asserted that the benchtop studies in this category are considered the industry standard and have been well accepted as the best way to compare single use and reusable bronchoscopes. In support of this assertion, the applicant provided six studies[64 65 66 67 68 69] as examples and indicated that there is no feasible way to accurately measure the flexion and deflection angles of a tool in vivo. Commenters supported the applicant's assertion and indicated that benchtop studies are standard and commonly utilized throughout the medical community. The applicant referenced results of one benchtop study (among the six examples referenced earlier) by Ho et al.,[70] published prior to the device's release. The study reviewed the published evidence on the applications of single-use (SU) and reusable bronchoscopes in bronchoscopy suites and intensive care units, and concluded that the portability, immediate availability, and theoretical reduced risk of clinically relevant infections confer an advantage of using SUFB over reusable FB in certain scenarios in the bronchoscopy and intensive care units. The applicant stated that improvements in maneuverability, angle tip deflection, and image quality are critical for a broader adoption of single-use FBs in more complex procedures.

Response: We thank the commenters for their input. While we maintain our belief that data which indicates that a device demonstrates substantial clinical improvements over currently available treatments in the clinical setting where it is most likely to be used is beneficial, we recognize that obtaining such data is not always feasible. After reviewing the information provided in the public comment, including clarifications from the applicant on the Kurman et al.[71] study, the additional six benchtop studies (as referenced above) supplied by the applicant, and the comments supporting the applicant's assertion that benchtop studies for bronchoscopes are considered to be the industry standard and have been well accepted as the best way to compare single-use and reusable bronchoscopes, we agree that the applicant's self-sponsored study by Kurman et al.[72] is sufficient to show improved clinical outcomes.

Comment: In response to our concern that the submitted evidence of substantial clinical improvement

[59] *Ibid.*

[60] 21 CFR part 807, subpart E.

[61] *Ibid.*

[62] Kurman, J., Wagh, A., Benn, B., & Islam, S. (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[63] *Ibid.*

[64] Liu, L., Wahidi, M., Mahmood, K., Giovacchini, C., Shofer, S., Cheng, G. (2020) Operator perception of a single-use flexible bronchoscope: comparison with current standard bronchoscopes. *Respiratory care, 65*(11):1655–1662. Doi: 10.4187/respcare.07574. Epub 2020 Jun 2. PMID: 32487752.

[65] Darrell, N., Grant, S., Abdurrahman, H., Matthew, N., Russell, M., et al. (2022). Operator perception of the performance of multiple single-use bronchoscopes compared to standard re-usable bronchoscope. *Am J Biomed Sci & Res, 17*(2). AJBSR.MS.ID: 002333, DOI: 10.34297/AJBSR.2022.17.002333.

[66] Lamb, C.R., Yavarovich, E., Kang, V. et al. (2022). Performance of a new single-use bronchoscope versus a marketed single-use comparator: a bench study. *BMC Pulm Med 22, 189*). Retrieved from: *https://bmcpulmmed.biomedcentral.com/articles/10.1186/s12890-022-01982-4.*

[67] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical care medicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[68] Liang, Z., Zhou, G., Li, Y. et al. (2022). Evaluation of a new developed disposable and portable bronchoscopy system. *BMC PulmMed 22, 136. https://doi.org/10.1186/s12890-022-01933-z.*

[69] Deasy, K.F., Sweeney, A.M., Danish, H., O'Reilly, E., Ibrahim, H., Kennedy, M.P. (2023). Single use or disposable flexible bronchoscopes: bench top and preclinical comparison of currently available devices. *J Intensive Care Med, 38*(6):519–528. Doi:10.1177/08850666221148645. Epub 2023 Jan 7. PMID: 36609193; PMCID: PMC10114257.

[70] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical care medicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[71] Kurman, J., Wagh, A., Benn, B., & Islam, S. (2023). A comparison of single-use bronchoscopes and reusable bronchoscopes for interventional pulmonology applications. Confidential. Ambu Inc., funded evaluation and testing.

[72] *Ibid.*

discussed potential adverse events from reusable bronchoscope procedures, but did not directly show any clinical improvement that resulted from the use of the Ambu® aScope™ 5 Broncho HD, the applicant reiterated that the single use nature of the Ambu® aScope™ 5 Broncho HD avoids the adverse issues and risk associated with reprocessing detailed in the articles referenced in its application as there is no reprocessing or reuse of the bronchoscope. The applicant noted that, the successful Uretero 1 device pass-through application included the Bozzini et al. study which does not include the nominated device as the comparator. The applicant stated that, in the same fashion as the Uretero 1 device pass-through application, the Ambu® aScope™ 5 Broncho HD application is using the transitive property to highlight that because clinical benefits can be seen with single-use endoscopes and the nominated device is single-use, the nominated device is therefore an improvement over reusable endoscopes. Another commenter referenced the CY 2023 OPPS/ASC final rule with comment period, wherein CMS approved the Uretero 1 device pass-through application and established device pass-through code HCPCS C1747 (Endoscope, single-use (that is, disposable), urinary tract, imaging/illumination device (insertable)). Specifically, the commenter pointed out that CMS stated that we agreed that the evidence demonstrating the improved patient outcomes and reduced patient risk associated with the disposable device in comparison with reusable devices represents substantial clinical improvement. This commenter suggested that this conclusion should also apply to single-use bronchoscopes as well. The commenters believed that single-use scopes reduce reprocessing-related bronchoscope infection risk, and that this risk reduction is a substantial clinical improvement.

Response: We appreciate the commenters' input. As the applicant and commenter indicated, CMS approved Uretero1 [73] for transitional pass-through payment status in the CY 2023 OPPS/ASC final rule with comment period. We note that we expressed similar concerns relating to the lack of comparative studies between the single-use Uretero1 device and other disposable devices and indicated that, while we ultimately agreed that the totality of evidence demonstrated improved patient outcomes and reduced patient risk associated with the disposable device in comparison with reusable devices represents substantial clinical improvement, it would have been helpful to see comparative studies. The applicant and the commenter seem to suggest that because we determined that the Uretero 1 device demonstrated substantial clinical improvement despite providing a study which does not include the nominated device as a comparator, that we should similarly determine that the type of evidence submitted by Ambu® aScope™ 5 Broncho HD represents substantial clinical improvement. We note that we do not believe that this implied approach to application evaluation is appropriate. Rather, we continue to believe that our current process wherein we evaluate all evidence submitted for each device pass-through application as it applies to the nominated device is appropriate. Due to inherent differences in the devices themselves and the supporting documentation submitted, CMS may have different concerns as they relate to the nominated device. In addition, we are not precluded from evaluating evidence and expressing concerns regarding evidence submitted in support of an application simply because that type of evidence has been submitted in support of a previous application. While we encourage applicants to read the application summaries presented in previous OPPS/ASC rules as they can help applicants determine the types of documentation that have been submitted and assess areas of potential concern with their technology, we caution applicants not to rely solely on the presumption that previously submitted types of evidence, evaluated for a different device, either need not be submitted or need not be fully addressed as it relates to their technology. Further, we encourage applicants to submit all relevant supporting evidence with their device pass-through application to allow us to adequately evaluate and include the data in the notice of proposed rulemaking.

With regard to our concern that the submitted evidence of substantial clinical improvement discussed potential adverse events from reusable bronchoscope procedures but did not directly show any clinical improvement that resulted from the use of the Ambu® aScope™ 5 Broncho HD, we indicated that it would be helpful to see published peer-reviewed comparative studies between the single-use Ambu® aScope™ 5 Broncho HD device and other disposable devices. After reviewing the information provided in the public comment, specifically the 2021 FDA safety notice,[74] the Ho et al.[75] study that supported the increased risks associated with using reusable devices, and the Kurman et al. study which distinguished the device from similar devices on the market and the earlier versions of the nominated device on the market, we agree that the evidence demonstrates there are improved patient outcomes and reduced patient risk associated with the single-use Ambu® aScope™ 5 Broncho HD device in comparison with reusable devices.

Comment: In response to the concern regarding the relevance of the 2015 FDA safety notice to the nominated device, specifically that the guidance appeared to apply to reprocessed flexible bronchoscopes broadly, not to disposable, single-use devices comparable to the nominated device, and that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection, the applicant submitted a 2021 FDA safety notice [76] showing FDA's analysis of Medical Device Reports (MDRs) related to infections or device contamination associated with reusable flexible bronchoscopes from 2015–2021. The document states that between January 2010 and June 2015, the FDA received 109 MDRs related to infections or device contamination associated with reusable flexible bronchoscopes, and between July 2015 and January 2021, the FDA received 867 additional MDRs. Of the 867 reports received between July 2015 and January 2021, there were seven reports of deaths. Since 2015, the number of MDRs relevant to infection or contamination submitted to the FDA has increased from under 100 per year to between 100–200 per year. In addition, the applicant noted that FDA received at

[73] In the CY 2023 OPPS/ASC final rule with comment period CMS approved Uretero1 as a new device category for transitional pass-through payment status and established HCPCS code C1747 as a new device category beginning in January 2023 (87 FR 7129 through 71934) effective January 1, 2023.

[74] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

[75] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical caremedicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[76] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

least 226 bronchoscope-related MDRs from July 2021 to July 2023. The applicant asserted that the latest MDR numbers highlight the sustained increase of these MDRs. The applicant also noted that the MDR system is a passive surveillance system and may undercount the true number of bronchoscope infections and/or contaminations.

In reference to CMS's concern regarding the relevance of the 2015 FDA safety notice, the applicant stated that CMS determined that a similar communication (FDA advisory notice) was sufficient to demonstrate substantial clinical improvement for Uretero 1 in CY 2023. The applicant further provided that compared to ureteroscopes, which received 450 reports from 2017–2021 (from roughly 600,000 cases per year), reusable bronchoscopes received 867 from 2015–2021 (out of roughly 500,000 cases per year). The applicant asserted that given CMS' previous acceptance of FDA guidance documents as evidence of substantial clinical improvement and the increased incidents of MDRs for bronchoscopes when compared to ureteroscopes, the bronchoscope MDR data provided must also be considered sufficient evidence.

A few commenters, including the applicant, pointed out that the supplemental update [77] issued on June 25, 2021, directly addresses the omission of single-use medical devices from the FDA safety communication [78] originally dated September 17, 2015, regarding infections associated with reprocessed flexible bronchoscopes. The commenters stated that the supplemental update urges health care providers to consider using single-use bronchoscopes in situations where there is an increased risk of spreading infection and recommends the use of sterilization instead of high-level disinfection for all flexible bronchoscope reprocessing. One commenter clarified that some reusable flexible bronchoscopes are physically incompatible with some or all sterilization methods, while others may be capable of withstanding the sterilization process, but the manufacturers have not provided a validated sterilization process in the 510(k) cleared device labeling. Another commenter stated that the single-use flexible bronchoscopes minimize the risk of patient cross-contamination and agreed with the applicant's assertation that reusable bronchoscopes frequently lead to issues of cross-contamination and infection because of complex designs and issues with reprocessing, especially for patients who are immunocompromised.

A few commenters also provided additional data on the prevalence of inadequately reprocessed bronchoscopes posing an increased risk of remaining contaminated and cross-infecting patients with multidrug-resistant organisms. One commenter cited a recently published peer-reviewed article by Mehta and Muscarella (2020),[79] which provides evidence both for the significance of this application and the prevalence of infection due to, among other risk factors, the inadequate reprocessing of reusable bronchoscopes. The primary objectives of the study were to investigate the risk of bronchoscopes transmitting infections of carbapenem-resistant Enterobacteriaceae (CRE) and related multidrug-resistant organisms (MDROs). This study's findings suggest that bronchoscopes may pose an under-recognized potential for transmission of CRE and related MDROs, warranting greater public awareness, enhanced preventive measures, and updated reprocessing guidance. Per the commenter, this study's data suggests that the cleaning and high-level disinfection of bronchoscopes performed in accordance with published guidelines and manufacturer instructions may not always be sufficiently effective to eliminate this risk. The study concluded that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection. Another commenter indicated that while it is important for hospitals to improve reprocessing practices in general, a clean reusable scope will never be as clean as a sterile, single-use scope, even following the most rigorous cleaning protocols. The commenter stated that while CMS highlighted the low number of reported infections given the number of bronchoscopies that occur each year, unlike many other types of endoscopes that enter a sterile or otherwise clean anatomy (ureter), patients who need a bronchoscopy often require such procedures due to potential infection which could mask bronchoscope-mediated transmission of infectious agents.

Response: We appreciate the applicant's and the commenters' responses and additional evidence. We found the data contained in the updated 2021 FDA safety notice [80] compelling. While FDA noted in the 2015 FDA safety notice submitted as part of the application that when compared to the number of bronchoscopy procedures performed in the U.S. each year this is considered a small number of MDRs, we agree with the applicant's assertion that the latest MDR numbers provided in the 2021 FDA safety notice [81] highlight the sustained increase of these MDRs. While we acknowledge some of the data limitations, after reviewing the information provided in the public comment and the 2021 FDA safety notice,[82] we agree with the commenters that reusable bronchoscopes present a risk of cross-infection due to contamination. We understand that despite strictly adhering to the manufacturers' recommendations for reprocessing, some bronchoscopes still show evidence of biofilms, which are a source of cross-contamination. The applicant and other commenters provided sources: Mehta and Muscarella (2020) [83] and the 2021 FDA safety notice,[84] that demonstrate that even ''properly'' re-processed bronchoscopes have positive microbial growth via reusable bronchoscopes which is mitigated by single-use bronchoscopes like Ambu aScope™ 5 Broncho HD sufficiently to demonstrate substantial clinical improvement in situations where there is an increased risk of spreading infection. After consideration of the public comments received, we believe that commenters have addressed our concerns regarding whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement criterion and that the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies due to compelling evidence from the applicant and other commenters as discussed above,

[77] *Ibid.*

[78] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[79] Mehta, A.C., Muscarella, L.F. (2020). Bronchoscope-related ''superbug'' infections. *Chest, 157*(2):454–469.

[80] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

[81] *Ibid.*

[82] *Ibid.*

[83] Mehta, A.C., Muscarella, L.F. (2020). Bronchoscope-related ''superbug'' infections. *Chest, 157*(2):454–469.

[84] FDA Safety Communications, Flexible Bronchoscopes and Updated Recommendations for Reprocessing: FDA Safety Communication, issued June 25, 2021. *https://www.fda.gov/medical-devices/safety-communications/flexible-bronchoscopes-and-updated-recommendations-reprocessing-fda-safety-communication.*

specifically the 2021 FDA safety notice [85] and Ho et al.[86] study that demonstrated the increased risks associated with using reusable devices

In response to the applicant's comments comparing the Uretero 1 application summary included in the CY 2023 OPPS/ASC final rule with comment period with the application summary for the nominated device included in this final rule with comment period, we note that we expressed a similar concern in the Uretero 1 application summary that the FDA advisory letter regarding ureteroscopes did not mention single-use devices and it was not clear how the recommendations in the letter supported the applicant's claims of substantial clinical improvement related to Uretero1. While we ultimately determined that evidence was sufficient to demonstrate substantial clinical improvement, we would like to reiterate that we evaluate all evidence submitted for each device pass-through application as it applies to the nominated device. While we agree that data provided regarding the increased incidents of MDRs for bronchoscopes and the nominated devices' impact of mitigating infection risk, we do not agree that CMS' previous acceptance of FDA guidance documents must be considered sufficient evidence of substantial clinical improvement for the nominated device. The ultimate determination of whether evidence demonstrates substantial clinical improvement for one application, while taken into consideration as appropriate, is not controlling on future determinations. Again, due to inherent differences in the devices themselves and the supporting documentation submitted, CMS may have different concerns as they relate to the nominated device. In addition, we are not precluded from evaluating evidence and expressing concerns regarding types of evidence submitted in support of an application simply because that type of evidence has been submitted in support of a previous application. As we stated previously, while we encourage applicants to read the application summaries presented in previous OPPS/ASC rules as they can help applicants determine the types of documentation that have been submitted and assess areas of potential concern with their technology, we caution applicants from relying solely on the presumption that previously submitted types of evidence, evaluated for a different device, either need not be submitted or need not be fully addressed as it relates to their technology. We encourage applicants to submit all relevant supporting evidence with their device pass-through application to allow us to adequately evaluate and include the data in the notice of proposed rulemaking.

Comment: In response to our concern that the Châteauvieux et al.[87] and Barron and Kennedy [88] studies suggested limiting the use of single-use bronchoscope devices to specific situations (that is, after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting, the applicant asserted that this recommendation was made due to the potential cost burdens of reusable scopes referenced in the study. The applicant further asserted that if cost was not a barrier and facilities widely adopted single-use bronchoscopes, such as the Ambu® aScope™ 5 Broncho HD, the benefits of advanced bronchoscopy procedures would be more accessible. One commenter, writing in support of approval of the nominated device for pass-through payment, expressed concern that the cost of Ambu® aScope™ 5 Broncho HD created a barrier to utilization, and agreed with the applicant that Châteauvieux et al.[89] and Barron and Kennedy [90] suggest limiting single-use scopes to specific case types because of cost. However, this commenter noted that studies by Maerkedahl et al., Mouritsen et al., and Kurman et al. all found that single-use scopes are economically advantageous relative to reusable scopes. This commenter stated that despite these findings, cost does admittedly remain a major barrier to broader adoption of single-use scopes. This commenter noted that improving reimbursement would help mitigate this barrier and allow more physicians to use the device for advanced bronchoscopy cases where it is now the preferred option. The applicant, in response to this comment indicated that, as this section (the substantial clinical improvement section under which the comment was submitted) is not about cost, it is not relevant to whether the Ambu® aScope™ 5 Broncho HD can provide a substantial clinical improvement.

Response: We appreciate the commenters' input. While the applicant did not provide in its application additional information about situations where use of single-use bronchoscopes would be optimal, we appreciate the insight provided from the applicant and several commenters who gave specific examples for how the device allows for advanced bronchoscopy procedures to be performed with a single-use scope, without concern for contamination, specifically for procedures that include but are not limited to: transbronchial biopsy, airway inspection for high-risk/immunocompromised patients, and procedures with high-frequency tools.

While we maintain our belief that further investigation with comparators in these specified cases would more directly establish whether the device demonstrates a substantial clinical improvement over currently available treatment options in the clinical setting where it is most likely to be used, we understand that this data may not be available. We agree with the commenters that Châteauvieux et al.[91] and Barron and Kennedy [92] studies suggested limiting the use of single-use bronchoscope device to specific situations, in part, due to cost considerations. After consideration of the public comments received, we agree that the evidence demonstrates that the device is a substantial clinical improvement over currently available treatment options in the clinical setting.

In addition, we thank the commenter for their input on how approval would impact existing barriers to broader adoption of single-use scopes. While the

[85] *Ibid.*

[86] Ho, E., Wagh, A., Hogarth, K., Murgu, S. (2022). Single-use and reusable flexible bronchoscopes in pulmonary and critical caremedicine. *Diagnostics, 12*(1):174. Retrieved from: *https://doi.org/10.3390/diagnostics12010174.*

[87] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[88] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[89] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[90] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[91] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[92] Barron, S.P., & Kennedy, M.P. (2020). Single-use (disposable) flexible bronchoscopes: the future of bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

applicant is correct that we do not assess cost in § 419.66(c)(2), CMS recognizes the importance of addressing cost as a barrier to utilization, and as stated in section 2.a., a goal of transitional pass-through is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629). We address the cost of Ambu® aScope™ 5 Broncho HD and the cost significance criteria below.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Ambu® aScope™ 5 Broncho HD would be reported with HCPCS codes listed in Table 87.

BILLING CODE 4150–28–P

TABLE 87: HCPCS CODES REPORTED WITH THE AMBU® ASCOPE™ 5 BRONCHO HD

HCPCS Code	Long Descriptor	SI	APC
31615	Tracheobronchoscopy through established tracheostomy incision	T	5162
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing	J1	5153
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with brushing or protected brushings	J1	5153
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial alveolar lavage	J1	5153
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial or endobronchial biopsy(s), single or multiple sites	J1	5153
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of fiducial markers, single or multiple	J1	5155
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), single lobe	J1	5154
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration biopsy(s). Trachea, main stem and/or lobar bronchus(i)	J1	5154
31630	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with tracheal/bronchial dilation or closed reduction of fracture	J1	5154
31631	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required	J1	5155
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed	J1	5155
31635	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of foreign body	J1	5153
31636	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of bronchial stent(s)(includes tracheal/bronchial dilation as required), initial bronchus	J1	5155
31638	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)	J1	5155
31640	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with excision of tumor	J1	5154
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)	J1	5154

HCPCS Code	Long Descriptor	SI	APC
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of catheter(s) for intracavitary radioelement application	J1	5153
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, initial	J1	5153
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, subsequent, sams hospital stay	T	5152
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	J1	5155
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), initial lobe	J1	5154
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration(s)/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures	J1	5154
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration(s)/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures	J1	5154
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J1	5155
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J1	5155
31785	Excision of tracheal tumor or carcinoma; cervical	J1	5165
32400	Biopsy, pleura, percutaneous needle	J1	5072
32550	Insertion of indwelling tunneled pleural catheter with cuff	J1	5341
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	J1	5182
32552	Removal of indwelling tunneled pleural catheter with cuff	Q2	5181
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	T	5181
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with computer-assisted, image-guided navigation	**	N/A
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration	**	N/A

HCPCS Code	Long Descriptor	SI	APC
	biopsy(s), each additional lobe (list separately in addition to code for primary procedure)		
31637	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, each additional major bronchus stented (list separately in addition to code for primary procedure)	**	N/A
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s)	**	N/A
31780	Excision tracheal stenosis and anastomosis; cervical	**	N/A
31781	Excision tracheal stenosis and anastomosis; cervicothoracic	**	N/A
31786	Excision of tracheal tumor or carcinoma; thoracic	**	N/A
32200	Pneumonostomy, with open drainage of abscess or cyst	**	N/A
32674	Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)	**	N/A
32815	Open closure of major bronchial fistula	**	N/A

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notification OPPS Addendum (87 FR 2060).

BILLING CODE 4150–28–C

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5152, which had a CY 2022 payment rate of $383.33 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We noted that the HCPCS code 31646 identified by the applicant had a device offset amount of $0.00 at the time the application was received. Accordingly, we are evaluating the cost significance requirements using $0.00 as the appropriate device offset amount. According to the applicant, the cost of the Ambu® aScope™ 5 Broncho HD is $799.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $799.00 for the Ambu® aScope™ 5 Broncho HD is 208.44 percent of the applicable APC payment amount for the service related to the category of devices of $383.33 (($799.00/$383.33) × 100 = 208.44 percent). Therefore, we stated that we believe the Ambu® aScope™ 5 Broncho HD meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). Given that there are no device-related costs in the APC payment amount, and the Ambu® aScope™ 5 Broncho HD has an estimated average reasonable cost of $799.00, we stated that we believe the Ambu® aScope™ 5 Broncho HD meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $799.00 for the Ambu® aScope™ 5 Broncho HD and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $799.00 by 208.44 percent ((($799.00 − $0.00)/$383.33) × 100 = 208.44 percent). Therefore, we stated that we believe the Ambu aScope™ 5 Broncho HD meets the third cost significance requirement.

We invited public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

We did not receive any comments with regard to any of the cost significance requirements specified at § 419.66(d). Based on our findings from the first, second, and third cost significant tests, we believe that the Ambu® aScopeTM 5 Broncho HD device

meets the cost significance criterion specified at § 419.66(d).

After consideration of the public comments we received and our review of the device pass-through application, we have determined that the Ambu® aScope™ 5 Broncho HD meets the criteria for device pass-through status. We are approving this application because the documentation (namely the FDA document and additional studies) that were submitted in response to the proposed rule address our concerns and provide evidence of substantial clinical improvement that is required. Therefore, we are approving the Ambu® aScope™ 5 Broncho HD for transitional pass-through payment status beginning January 1, 2024.

(b) Praxis Medical CytoCore

Praxis Medical, LLC submitted an application for a new device category for transitional pass-through payment status for Praxis Medical CytoCore (CytoCore) for CY 2024. Per the applicant, CytoCore is a single-use disposable biopsy instrument. Per the applicant, at the time of biopsy, the motorized CytoCore device contains gears and an internal motor that spins a minimally invasive needle to increase cellular yields in fewer passes. The applicant further explained that CytoCore is vacuum-assisted and can easily be operated using one hand. According to the applicant, the primary use is for biopsy of any suspicious thyroid nodule.

The applicant stated that the CytoCore Biopsy Instrument device package includes: (1) a single CytoCore biopsy instrument, powered by an alkaline type battery; (2) three luer adaptors; (3) a 5ml syringe; and (4) an instructions for use (IFU) booklet. Per the applicant, the CytoCore is compatible with disposable needles of 22-to-25-gauge and 4-to-10-cm length that are intended for soft tissue biopsy procedures (needles are not included in the device package). The applicant further explained that only the CytoCore luer adapters and syringes provided by Praxis can be used on CytoCore and that the CytoCore luer adapters can only be used with the CytoCore Biopsy Instrument.

Per the applicant, the operator of CytoCore can direct the needle and draw back the plunger with only one hand, thereby diminishing the need to move the needle in an in-and-out motion to harvest cells. As with other types of biopsies, the sample collected can help make a diagnosis or rule out conditions such as cancer. The applicant claimed that CytoCore enables the physician to collect more cellular material in fewer passes and reduce the number of repeat biopsies and surgeries resulting from inadequate cellular samples obtained using standard fine needle aspiration (FNA). According to the applicant, CytoCore is designed to collect enough DNA for pathology to definitively rule in or out cancer and inform subsequent treatment at the time of the first biopsy. Per the applicant, studies report nondiagnostic rates for biopsies to be as high as 30 to 50 percent using FNA biopsy.[93]

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on March 31, 2020, the applicant received 510(k) clearance from FDA for CytoCore for use as a device to hold a syringe for performing a biopsy of an identified mass with one hand. We received the application for a new device category for transitional pass-through payment status for CytoCore on August 31, 2022, which is within 3 years from the date of the initial FDA marketing authorization.

We invited public comments on whether CytoCore meets the newness criterion at § 419.66(b)(1).

We did not receive public comments regarding whether CytoCore meets the newness criterion at § 419.66(b)(1). We received the application for a new device category for transitional pass-through payment status for CytoCore on August 31, 2022, which is within 3 years of the initial FDA marketing authorization on March 31, 2020, and as such, we have concluded that CytoCore meets the newness criterion.

With respect to the eligibility criterion at § 419.66(b)(3), the applicant did not assert whether CytoCore is integral to the service provided. According to the applicant, CytoCore is used for one patient only. Per the applicant, CytoCore comes into contact with human tissue and is surgically inserted via the syringe attached to the motorized CytoCore device. Per the applicant, CytoCore is used with a 22-to-25-gauge standard fine needle (not included in the device package), which is inserted into human tissue to collect cellular samples. The applicant stated that the fine needle is attached to CytoCore, inserted into the nodule, and cellular material is collected through the needle into the syringe. The applicant further explained that the cellular material is visible in the hub of the needle or the luer adapter. However, we noted that the motorized CytoCore device itself is not surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3). Further, we noted that according to the FDA 510(k) Summary and Indication for Use, CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand and that the device never comes in contact with the patient.

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CytoCore is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets. The applicant also did not address whether CytoCore is a supply or material furnished incident to a service or whether the device is surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required by § 419.66(b)(3). However, in the CY 2000 OPPS interim final rule with comment period (65 FR 67804 and 67805), we explained how we interpret the exclusion criterion at § 419.66(b)(3). We stated that we consider a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 OPPS final rule with comment period (70 FR 68516, 70 FR 68629 and 68630), we adopted as final our interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the

[93] CMS made minor edits to the device description in this final rule with public comment to improve clarity.