

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

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ADVISORY PANEL ON HOSPITAL OUTPATIENT PAYMENT

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MEETING

+ + + + +

MONDAY  
AUGUST 25, 2025

+ + + + +

The Advisory Panel met via  
Videoconference at 9:30 a.m. EDT, Dr. Edith  
"E.L." Hambrick, Chair, presiding.

PRESENT

EDITH "E.L." HAMBRICK, M.D., J.D., Chair  
JENNIFER ARTIGUE, RHIT, CCS  
BECKY BEAN, B.S., M.H.A./M.B.A., Pharm.D.  
NANCY DAWSON, M.D., FACP  
BLAKE DIRKSEN, M.S., DABR  
BRANDON FAZIO, B.S.  
SCOTT MANAKER, M.D., Ph.D.  
RAHUL SETH, D.O., FASCO  
WENDI SMITH LLOYD, CPC, COC, CPMA, COSC  
WILLIAM TETTELBACH, M.D., FACP, FIDSA, FUHM,  
MAPWCA, CWSP  
CAROLINE ZELLER, D.D.S., M.P.H.

1 STAFF PRESENT

2 ABIGAIL CESNIK, Designated Federal Officer,  
Division of Outpatient Care

3 MITALI DAYAL, Deputy Director, Division of  
Outpatient Care

4 TONYA GIERKE, Division of Outpatient Care

MOLLY MacHARRIS, Acting Deputy Director,  
5 Hospital and Ambulatory Policy Group

GIL NGAN, Division of Outpatient Care

6 DAVID RICE, Director, Division of Outpatient  
Care

7 SCOTT TALAGA, Division of Outpatient Care

GINA AUGHENBAUGH

8 RUSSELL BAILEY

ELISE BARRINGER

9 BRIAN CARLSON

ERICK CHUANG

10 ALLIE D'ACCURZIO

MARVELYN DAVIS

11 GARY DELHOUGNE

JOLAYNE DEVERS

12 TA-YUAN HO

SEAMUS JACKSON

13 STEVE LEE

YAJUAN LU

14 NICOLE MARCOS

RODRIGO MODOLO

15 STEVEN SIEGEL

WENDI SMITH

16 DANA TREVAS

KRISTEN TULLIA

17 NATE VERCAUTEREN

18 ALSO PRESENT:

19 MARSHALL BEDDER, Neuralace Medical

BRANDON BENTZLEY, M.D., Ph.D., Magnus Medical

20 MARIA BREITENFELDT, Pulmonx

EVELYN GITTINGER, EGMCC, LLC

21 ERIC GREIG, Cooley LLP

ROBERTA GUTHERY, Intuitive Surgical

22 STUART LANGBEIN, Hogan Lovells

LINDA UPCHURCH, AngioDynamics

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P-R-O-C-E-E-D-I-N-G-S

(9:31 a.m.)

DR. HAMBRICK: Good morning. My name is Edith Hambrick, and I'm the Chairperson of the Hospital Outpatient Payment Advisory Panel. I would like to extend a hearty Centers for Medicare & Medicaid Services welcome to the 2025 meeting of the Advisory Panel on Hospital Outpatient Payment.

With us today through Zoom, we have presenters, commenters, and members of the public. We welcome and look forward to your presentations and comments.

First, I would like to let the panel members introduce themselves now. I'd like to have the panel members introduce themselves, and you can go in alphabetical order, as depicted on the screen.

We'll start with Ms. Artigue.

(No response.)

DR. HAMBRICK: Okay. Maybe she's having trouble getting in.

1                   How about you, Dr. Bean?

2                   DR. BEAN:  Hey, good morning, everyone.

3                   My name is Becky Bean.  I am the Senior Vice  
4                   President of Integrated Care Solutions with  
5                   Novant Health, and I'm grateful to be a part of  
6                   the HOP panel.

7                   So, I'll pass it on to Nancy Dawson.

8                   DR. DAWSON:  Thank you, Becky.  I'm Dr.  
9                   Nancy Dawson.  I'm an internal medicine  
10                  physician at Mayo Clinic in Jacksonville,  
11                  Florida.

12                  MR. DIRKSEN:  My name is Blake Dirksen.  
13                  I'm a medical physicist from the University of  
14                  Iowa.

15                  MR. FAZIO:  Hi.  I'm Brandon Fazio,  
16                  Senior Director of Finance for Community Health  
17                  Systems here in Franklin, Tennessee.

18                  DR. MANAKER:  Good morning.  I'm Scott  
19                  Manaker.  I'm a pulmonary and critical care  
20                  physician at the University of Pennsylvania in  
21                  Philadelphia.

22                  DR. SETH:  Good morning.  My name is

1 Dr. Rahul Seth. I'm a medical oncologist at  
2 Upstate Medical University in Syracuse, New  
3 York.

4 MS. SMITH: I'm Wendi Smith Lloyd. I'm  
5 a Senior Internal Coding Consultant in the  
6 Louisiana-based Ochsner Health System.

7 DR. TETTELBACH: Good morning. My name  
8 is William Tettelbach. I am board-certified in  
9 undersea and hyperbaric medicine, internal  
10 medicine, as well as infectious diseases, and  
11 certified in wound care. I'm the Chief Medical  
12 Officer for RestorixHealth, as well as hold an  
13 appointment at Duke University in the Department  
14 of Anesthesiology.

15 DR. ZELLER: Good morning. Caroline  
16 Zeller, Hospital Dentist at Oregon Health and  
17 Science University.

18 MS. ARTIGUE: Dr. Hambrick, can you  
19 hear me now?

20 DR. HAMBRICK: Now we can, Ms. Artigue,  
21 yes.

22 MS. ARTIGUE: Good morning. This is

1 Jennifer Artigue from Franciscan Missionaries of  
2 Our Lady Health System, Louisiana-Mississippi,  
3 overseeing HIM coding and documentation  
4 improvement. Looking forward to the meeting.

5 DR. HAMBRICK: Thank you.

6 I'd like to acknowledge Ms. Molly  
7 MacHarris, who is the Acting Deputy Director of  
8 the Hospital and Ambulatory Policy Group, whom  
9 we will hear from later.

10 Just a few words from me. So, the  
11 returners, you've heard them before. So, get  
12 ready. The final rule for the Hospital  
13 Inpatient Prospective Payment System for Fiscal  
14 Year 2026 was published in the Federal Register  
15 on August 4th, 2025.

16 The Notice of Proposed Rulemaking for  
17 the Hospital Outpatient Prospective Payment  
18 System Ambulatory Surgical Centers for calendar  
19 year 2026 was published in The Federal Register  
20 on July 17, 2025. That's 90 Federal Register  
21 page 33476. If you wish to comment, comments  
22 must be submitted by September 15th, 2025.



1           The Notice of Proposed Rulemaking for  
2     the Medicare Physician Fee Schedule for calendar  
3     year 2026 was published in The Federal Register  
4     on July 16th, 2025. That's 90 Federal Register  
5     32352. If you wish comment, comments must be  
6     submitted by 5:00 p.m. September 12, 2025.

7           Now we'll talk about the charter. The  
8     panel shall advise the Secretary and the  
9     Administrator of CMS about the clinical  
10    integrity of the APC groups and their associated  
11    weight. The panel is technical in nature and it  
12    will deal with such issues as addressing whether  
13    procedures are similar, both clinically and in  
14    terms of resource use; assigning new Current  
15    Procedural Terminology (CPT) codes, or HCPCS  
16    codes to APCs; reassigning codes to different  
17    APCs; reconfiguring the APCs into new APCs;  
18    evaluating the required level of supervision for  
19    hospital outpatient services, OPPS APC rates for  
20    covered ASP procedures, et cetera.

21           The subject matter is limited to these  
22    and related topics. Unrelated topics are not

1 subjects for discussion. Unrelated topics  
2 include, but are not limited to, the conversion  
3 factor, charge compression, passthrough payments  
4 for medical devices and drugs, wage adjustments,  
5 the types of practitioners who are permitted to  
6 supervise outpatient services, and the like.

7 A copy of the charter is available on  
8 the website with today's materials.

9 The panel will hear presentations and  
10 comments primarily related to the calendar year  
11 2025 final rule and the calendar year 2026  
12 Notice of Proposed Rulemaking. Comments that  
13 are not primarily related to those rules may be  
14 ruled out of order.

15 Now let's walk through the 2X rule.  
16 Section 1833(t)(2) of the Social Security Act  
17 provides that, subject to certain exceptions,  
18 the items and services within an APC group  
19 cannot be considered comparable with respect to  
20 the use of resources if the highest mean cost  
21 for an item or service in the group is more than  
22 two times greater than the lowest mean cost for

1 the item or service within the same group --  
2 referred to as the 2X rule.

3 In general, we use the geometric mean  
4 cost of the item or service in implementing this  
5 provision. The statute authorizes the Secretary  
6 to make exceptions to the 2X rule in unusual  
7 cases, such as low-volume items and services.

8 In the supporting documentation, there  
9 you will find a 2X listing. The 2X data to  
10 which I will be referring is the one using data,  
11 as noted in the proposed rule.

12 If you turn to pages 14 to 15, APC  
13 5052, this is an example of an APC with no 2X  
14 violation. The lowest mean cost is 17004 at  
15 \$280.14 -- that's on page 11 -- and the highest  
16 is CPT Code 13132 at \$553.20, which is on page  
17 15.

18 Now we'll have an example where there  
19 is a 2X violation. That's APC 5071, pages 20 to  
20 22. The lowest CPT code, the CPT code with the  
21 lowest mean cost is 19000 and \$515.13 on page  
22 21, and the highest is 19283 at \$1,104.46.

1       That's a 2X violation.

2               Oral presentations should not exceed  
3       five minutes in length for an individual or  
4       organization. The chair may further limit time  
5       allowed for presentations due to the number of  
6       oral presentations, if necessary.

7               In addition to formal presentations,  
8       there will be an opportunity during the meeting  
9       for public oral comments that will be limited to  
10      one minute for each individual and a total of  
11      three minutes per organization.

12              Please queue up, as instructed by our  
13      moderator, Ms. Marvelyn Davis, if you wish to  
14      address the panel. Please clearly identify  
15      yourself and your organization, if applicable,  
16      before speaking.

17              Are there any questions before we get  
18      started?

19              Okay. Then, in that case, we will now  
20      hear from Ms. Molly MacHarris, who is the Acting  
21      Deputy Director of the Hospital and Ambulatory  
22      Policy Group.

1 MS. MacHARRIS: Oh, thank you. Can you  
2 hear me now? Sorry about that.

3 DR. HAMBRICK: Yes, we can.

4 MS. MacHARRIS: Okay. Sorry. So, yes,  
5 thank you again, Dr. Hambrick. And good  
6 morning, everyone. I'm Molly MacHarris, the  
7 Acting Deputy Director of the Hospital and  
8 Ambulatory Policy Group. I'm really pleased to  
9 be able to welcome you all to the 2025 Advisory  
10 Panel on Hospital Outpatient Payments, also  
11 known as the HOP Panel.

12 This is the 38th meeting of the HOP  
13 Panel since its inception in 2001 and, as  
14 always, we, CMS, appreciate the panel's  
15 expertise and value its contribution to improve  
16 CMS policy by strengthening the connection  
17 between Medicare payments and patient-centered  
18 efficient care for our beneficiaries.

19 Shortly, David Rice, the Director of  
20 the Division of Outpatient Care, and Mitali  
21 Dayal, the Deputy Director of the Division of  
22 Outpatient Care, will provide a policy overview

1 of last year's OPPS/ASC final rule, as well as  
2 the recently published proposed rule, which is  
3 still in its public comment period.

4 Now I would like to say a few words  
5 about the HOP Panel. First, CMS has long  
6 recognized the importance of the public's role  
7 in developing effective policies, and we count  
8 on the assistance of advisory panels like this  
9 one for the diverse perspectives and expertise.

10 Additionally, these advisory committees  
11 ensure that public involvement and transparency  
12 are part of the federal policymaking process.

13 This specific panel is charged with  
14 advising the Secretary and the Administrator on  
15 the clinical integrity of APC groups and their  
16 associated group weights for the OPPS.

17 And with the renewal of the panel  
18 Charter in November of 2018, the panel may, in  
19 their deliberation of OPPS payment rates, also  
20 consider that covered procedures within the ASC  
21 payment system are, in fact, impacted by the  
22 OPPS APC groups and their associated weights.

1           The fundamental components of the OPPS  
2     have had a significant impact and effect on  
3     CMS's ability to support beneficiary choice,  
4     lower beneficiary costs, and promote high-  
5     quality and efficient hospital outpatient  
6     services. We greatly value the HOP Panel's  
7     recommendations on this important payment  
8     system.

9           And at this time, I would like to  
10    personally thank and recognize all of the  
11    members of the HOP Panel for contributing their  
12    time and expertise. Thank you.

13           We are always looking for new panel  
14    members and invite you to nominate yourself or  
15    someone you think would be a great asset to the  
16    HOP Panel moving forward.

17           Finally, we hope that you will take  
18    advantage of this opportunity to discuss and  
19    engage with the issues before the panel. I  
20    encourage everyone to share your feedback in the  
21    form of written public comments to the proposed  
22    rules by the September 15th deadline, so that

1 your important feedback can be considered in the  
2 development of the final rule.

3 I look forward to this year's  
4 discussion. And with that, I will turn it over  
5 to Abby for technical meeting reminders. Thank  
6 you.

7 MS. CESNIK: And thank you. Good  
8 morning. I'm Abby Cesnik, the Designated  
9 Federal Officer for this year's HOP Panel  
10 meeting. Welcome. We're happy to have you here  
11 today virtually. I'd like to go over some brief  
12 technical reminders.

13 So, first, to presenters and HOP Panel  
14 members, please remember to stay on mute when  
15 you're not speaking. When we get to the  
16 portions of the meeting when the public can make  
17 comments or ask questions, please use the Raise  
18 Hand feature in Zoom or type a question into the  
19 chat. If you have chosen to only dial into Zoom  
20 without entering your participant ID, we will  
21 not be able to unmute your line.

22 If you are a presenter, welcome. We



1 look forward to hearing your presentations.

2 Please cue us when you're ready for the next  
3 slide so we can advance it for you.

4 You're welcome to turn on your camera  
5 during your presentation, but please turn it off  
6 when you are not speaking.

7 As a reminder, you have five minutes  
8 for your presentation. A member of our staff  
9 will speak and let you know when you have one  
10 minute remaining and when you have reached your  
11 full time.

12 We would like to remind everyone that  
13 this meeting and the chat boxes are both being  
14 recorded.

15 Finally, if you need Zoom technical  
16 assistance, please write to us using the chat  
17 feature on Zoom or send an email to our Zoom  
18 operator, Marvelyn Davis. If you have other  
19 questions related to the meeting, please email  
20 the APC Panel mailbox, and we will be including  
21 both email addresses in the chat.

22 So, thanks, everyone, for joining us

1       today. And now, I'll turn it over to David  
2       Rice.

3               MR. RICE: Thanks, Abby.

4               Hi, everyone. I'm David Rice, the  
5       Director of the Division of Outpatient Care, and  
6       Mitali Dayal, the DOC's Deputy Director, and I  
7       will be giving a brief overview of the two OPPS  
8       rules that have been published since the last  
9       HOP meeting in August of 2024.

10              First, I'd like to acknowledge all of  
11      the folks in DOC whose hard work has allowed us  
12      to host this meeting. You'll see their names  
13      listed on the current slide, and you'll be  
14      hearing from many of them during presentations  
15      later today.

16              Moving to the next slide, I'd also like  
17      to note, as always, that the OPPS is a  
18      prospective payment system, not a fee schedule,  
19      and that items and services paid under the OPPS  
20      are paid based on groupings of items and  
21      services that have similar costs and that are  
22      clinically similar.

1           Moving to last year's final rule, the  
2           calendar year 2025 OPPS/ACS final rule displayed  
3           on November 1st, 2024, and I'll mention a few  
4           brief OPPS and ASC items that were included in  
5           this rule.

6           First, in accordance with Medicare law,  
7           CMS is finalizing an update to the OPPS payment  
8           rates for hospitals by 2.9 percent. This update  
9           was based on a projected market basket  
10          percentage increase of 3.4 percent, reduced by a  
11          half percentage point for a productivity  
12          adjustment.

13          In the 2019 OPPS final rule, CMS  
14          finalized a proposal to apply the productivity-  
15          adjusted hospital market basket update to ASC  
16          payment system rates for five years, and then  
17          extended that for an additional two years using  
18          that update, that 2.9 percent rate, also applied  
19          to ASCs.

20          Under the OPPS, the payment for  
21          diagnostic radiopharmaceuticals was packaged  
22          into the payment for nuclear medicine tests that

1 they were used with. While that payment  
2 approach generally works appropriately to  
3 sufficiently support efficient care, we  
4 recognize that in some specific circumstances,  
5 the payment amount for nuclear medicine tests  
6 may not have adequately accounted for the cost  
7 of certain high-cost diagnostic  
8 radiopharmaceuticals, even when those agents may  
9 be the most clinically appropriate.

10 Consequently, we finalized changes to  
11 the existing packaging policy to improve the  
12 accuracy of the overall payment amounts by  
13 paying separately for any diagnostic  
14 radiopharmaceutical with a per-day cost greater  
15 than \$630 and removed the cost of those payment  
16 amounts from the nuclear medicine APCs.

17 All qualifying products are paid at  
18 mean unit cost, and any diagnostic  
19 radiopharmaceutical with a per-day cost equal to  
20 or below that threshold continues to be policy  
21 packaged with payment for the nuclear medicine  
22 tests.

1 CMS also finalized the implementation  
2 of Section 4135 of the Consolidated  
3 Appropriations Act of 2023, which provides  
4 temporary additional payments for certain non-  
5 opioid treatments for pain relief in the  
6 hospital outpatient department in ASC settings  
7 from January 1, 2025, through December 31st,  
8 2027.

9 CMS implemented several statutory  
10 provisions, including evidence requirements for  
11 medical devices and the requirements for the  
12 FDA-approved indications.

13 To implement the statutory payment  
14 limitation under which the additional payment  
15 must not exceed the estimated average of 18  
16 percent of the OPPS payment for an OPPS service  
17 or a group of services, the estimated -- with  
18 which the non-opioid treatment for pain relief  
19 is furnished, CMS finalized our proposal to  
20 utilize the top five OPPS procedures by volume  
21 for each non-opioid drug or device to calculate  
22 the payment limitation.

1 CMS also finalized drugs and devices  
2 that qualify as non-opioid treatments for pain  
3 relief, and these products are paid separately  
4 in both the outpatient and ASC settings,  
5 starting in calendar year 2025. The qualifying  
6 drugs have FDA-approved indications to reduce  
7 postoperative pain and to reduce post-surgical  
8 analgesia, and the qualifying medical devices  
9 have demonstrated through evidence that they  
10 reduce opioid usage when used in the  
11 postoperative setting.

12 Finally, I want to mention that CMS  
13 excluded cell and gene therapies from  
14 Comprehensive-APCs in last year's final rule.  
15 CMS usually makes a single prospective payment  
16 based on the cost of all individual reported  
17 codes that appear on a claim with a primary  
18 Comprehensive-APC service, which we believe  
19 represents the provision of a primary service  
20 and all adjunctive services provided to support  
21 the delivery of that primary service.

22 However, there were rare instances of

1 cell and gene therapies, which are usually  
2 separately payable under the OPPS appearing on  
3 the same claim as a primary C-APC service, and  
4 therefore, having their payment packaged with  
5 the payments of the primary APC service.

6 We finalized a policy not to package  
7 those payments for cell and gene therapies into  
8 the C-APCs when those therapies are not  
9 functioning as integral ancillary support of  
10 dependent or adjunctive to the primary service.

11 For new cell and gene therapy products,  
12 we now add their product-specific HCPCS code to  
13 the C-APC and exclusion list, so that the  
14 payment for the very high-cost chimeric antigen  
15 receptor, CAR, T-cell and other gene therapies  
16 are not inadvertently packaged into the C-APCs.

17 And now I will pass this off to Mitali  
18 to walk through the calendar year 2026 OPPS/ASC  
19 proposed rule.

20 MS. DAYAL: Thanks, Dave. I'm Mitali  
21 Dayal, and I'll be covering the major proposals  
22 in the calendar year 2026 OPPS/ASC proposed

1 rule, which went on display on July 15th, 2025.  
2 We are currently in the 60-day public comment  
3 period which ends on September 15th, 2025. And  
4 the calendar year final rule will be targeted  
5 for display on or before November 1st, 2025.

6 Now I'll be covering the major  
7 proposals for the calendar 2026 proposed rule.  
8 In accordance with Medicare law, CMS proposes  
9 updating OPPS and ASC payment rates for  
10 hospitals and ASCs that meet applicable quality  
11 reporting requirements by 2.4 percent. And that  
12 update is based on the projected hospital market  
13 basket increase of 3.2 percent, reduced by an .8  
14 productivity adjustment.

15 Next is our proposal expanding the  
16 method to control unnecessary increases in the  
17 volume of outpatient services. For calendar  
18 year 2026, CMS is proposing to expand the  
19 calendar year 2019 policy of controlling  
20 unnecessary increases in the volume of the  
21 clinic service furnished in excepted off-campus  
22 provider-based departments, to include drug



1 administration services furnished in excepted  
2 off-campus provider-based departments.

3 Specifically, CMS is proposing to apply  
4 the Physician Fee Schedule equivalent payment  
5 rate for any HCPCS code assigned to the drug  
6 administration ambulatory payment  
7 classifications when it's provided at an off-  
8 campus provider-based department that's excepted  
9 from Section 603 of the Bipartisan Budget Act of  
10 2015.

11 CMS is also including a comments  
12 solicitation on expanding the agency's method to  
13 control unnecessary increases in the volume of  
14 the clinic service provided in on-campus  
15 hospital outpatient departments.

16 Next slide. CMS is proposing to phase  
17 out the inpatient-only list over a three-year  
18 period, beginning with removing 285 mostly  
19 musculoskeletal procedures for calendar year  
20 2026, and for expanding the ASC Covered  
21 Procedures List, CMS is proposing to revise the  
22 ASC Covered Procedures List criteria to modify

1 the general standard criteria and eliminate five  
2 of the general exclusion criteria, moving them  
3 into a new section for non-binding physicians'  
4 considerations of patient safety.

5 As a result of these criteria changes,  
6 CMS is proposing to add 276 procedures to the  
7 ASC Covered Procedures List, and CMS is also  
8 proposing to add an additional 271 codes to the  
9 ASC Covered Procedures List that are proposed  
10 for removal from the inpatient-only list for  
11 calendar year 2026.

12 Next slide, please. Next, I'll discuss  
13 the adjustment to payments for non-drug items  
14 and services to offset the increased payment for  
15 non-drug items and services made in calendar  
16 years 2018 through 2022 as a result of the 340B  
17 payment policy.

18 The 340B Final Remedy Rule codified a  
19 .5 percent reduction in the OPPS conversion  
20 factor applicable to non-drug items and services  
21 beginning in calendar year 2026, excluding  
22 hospitals that enrolled in Medicare after

1 January 1st, 2018. This .5 percent reduction  
2 would have remained in effect until the  
3 estimated aggregate payment reduction reached  
4 the \$7.8 billion of increased non-drug item and  
5 service payments made from calendar years 2018  
6 through 2022, which CMS estimated would occur in  
7 2041.

8 However, CMS has determined that a  
9 shorter timeframe is more appropriate. And for  
10 calendar year 2026, we are proposing to revise  
11 the annual offset percentage for non-drug items  
12 and services from .5 percent to 2 percent,  
13 effective 2026, excluding hospitals that  
14 enrolled in Medicare after January 1st, 2018.  
15 This 2 percent reduction would remain in effect  
16 until the estimated payment reduction reaches  
17 \$7.8 billion, which CMS estimates would occur in  
18 calendar year 2031.

19 In recent years, there has also been  
20 rapid development in the use of software-based  
21 technology to support clinical decision-making  
22 in the outpatient and physician office setting.

1 Medicare refers to these software-based  
2 technologies as software as a service.

3 For calendar year 2026, CMS is  
4 soliciting comments from the public on payment  
5 policies for these services under the OPPS,  
6 including applicable lessons learned from risk-  
7 bearing payment arrangements and input that  
8 helps incorporate the underlying value of  
9 technologies within medical practice into  
10 payment policy.

11 Next slide, please. And finally, for  
12 calendar year 2026, CMS is proposing to  
13 unpackage skin substitute products from  
14 application services and establish several APCs  
15 based on relevant product characteristics rather  
16 than based on stated prices for the provision of  
17 these products when they are used during a  
18 covered application procedure paid under the  
19 OPPS.

20 Secondly, CMS is also proposing to  
21 align skin substitute categorization consistent  
22 with their FDA regulatory status, such as 361

1 Human Cells, Tissues, and Cellular Tissue-Based  
2 Products and device types, premarket approvals,  
3 and 510(k)s.

4 We note that, for calendar year 2026,  
5 CMS is proposing to use a single payment rate  
6 for these three categories of skin substitute  
7 products to ensure that we are not  
8 underestimating the resources involved with  
9 furnishing these services.

10 CMS is proposing to implement these  
11 policy changes in both the hospital outpatient  
12 departments and physician office settings to  
13 remain consistent across different settings of  
14 care.

15 Those are the main proposals for the  
16 calendar year 2026 OPPS/ASC proposed rule. And  
17 with that, I'll pass it back to Dr. Hambrick.

18 Thank you.

19 DR. HAMBRICK: Thank you very much.

20 Are there any questions for Mr. Rice or  
21 Ms. Dayal?

22 Okay. Hearing none, we are going to go

1       into our subcommittee reports. We're going to  
2       start with the Business and Observation  
3       Subcommittee Report from Dr. Bean.

4               DR. BEAN: Hey, good morning,  
5       everybody. The Business and Observation  
6       Subcommittee met on August 25th. In that  
7       meeting, we discussed visits. The Subcommittee  
8       data for frequency and mean cost for visits were  
9       discussed. The Subcommittee data for  
10      observation services, claim frequency by month,  
11      and day of week were discussed. And the  
12      Subcommittee data for observation claims greater  
13      than 48 hours were discussed.

14              There were no public presentations for  
15      the Subcommittee this year. We discussed  
16      folding the Visits and Observations Subcommittee  
17      into the Data and APC/SI Subcommittees next  
18      year. All Subcommittee members present were in  
19      agreement with no longer separately holding a  
20      Visits and Observations Subcommittee meeting and  
21      producing visits and observation data reports  
22      for the Subcommittee.

1 DR. HAMBRICK: Thank you. Are there  
2 any questions for Dr. Bean or any of the other  
3 Subcommittee members on the Business and  
4 Observations Subcommittee?

5 MS. DAVIS: Currently, there are no  
6 raised hands.

7 DR. HAMBRICK: If not, I'll accept --  
8 thank you. I'll accept a motion to accept the  
9 Subcommittee report -- minutes, I'm sorry, as  
10 presented.

11 DR. SETH: Motion.

12 DR. MANAKER: Second.

13 DR. HAMBRICK: Any discussion?

14 All those in favor signify by saying  
15 aye.

16 (Chorus of aye.)

17 DR. HAMBRICK: Opposed? Okay. Any  
18 opposed signify by saying nay. And any  
19 abstentions? Thanks very much.

20 Now we'll move on to the Ambulatory  
21 Payment Classification, APC, Group and Status  
22 Indicator Subcommittee Report. That will be

1       given to us by Dr. Seth.

2               DR. SETH: Good morning and welcome.

3       Our committee, as stated before, met last week.

4       We reviewed several presentations, and we will

5       look forward to hearing the presentations today.

6       We decided to hear the presentations before

7       making any final recommendations.

8               So, thank you. Shall we begin?

9               DR. HAMBRICK: Thank you.

10              Are there other questions for Dr. Seth

11      or any of the other Subcommittee members?

12              I'll accept a motion --

13              MS. DAVIS: Currently, there are no

14      raised hands.

15              DR. HAMBRICK: Thank you. I'll accept

16      a motion to accept the report and to continue

17      the Subcommittee as currently being constituted.

18              DR. MANAKER: So moved.

19              DR. DAWSON: Second.

20              DR. HAMBRICK: Any discussion?

21              All those in favor, signify by saying

22      aye.



1 (Chorus of aye.)

2 DR. HAMBRICK: Any opposed, nay. Any  
3 abstentions?

4 Thank you very much, Dr. Seth.

5 And lastly, we'll hear from the Data  
6 Subcommittee. Dr. Tettelbach will present the  
7 report.

8 DR. TETTELBACH: Yes. Hello. We had  
9 the Data Subcommittee on August 15th. We had  
10 the members in attendance. During this meeting,  
11 the staff presented the claims accounting  
12 process that was used to develop the CY 2026  
13 OPPS NPRM payment rates and, you know, we  
14 answered questions from the Subcommittee  
15 members.

16 The Subcommittee discussed the cost  
17 changes associated with the APCs fluctuating by  
18 greater than 10 percent between the CY 2025 OPPS  
19 final rule and the CY 2026 OPPS proposed rule.

20 The Subcommittee also discussed the HOP  
21 presentation overview and deferred any  
22 recommendations to the 2025 HOP meeting. This

1 included the neurostimulator APC series,  
2 LivaNova, and then, MicroTransponder, and  
3 Neuromodulation Payment Policy Coalition  
4 complexity adjustment, you know, involving or  
5 overviews of Boston Scientific, Advamed, and  
6 Johnson & Johnson.

7 The Data Subcommittee voted to continue  
8 receiving the following documents for the next  
9 year's HOP Panel: the claims accounting  
10 overview for the CY 2027 OPPS NPRM and a file  
11 displaying the APCs with greater than plus/minus  
12 10 percent difference in payment rates between  
13 the CY 2026 OPPS final rule and the CY 2027 OPPS  
14 NPRM.

15 So, we also had a vote within that, and  
16 the current Chair was voted to remain the Chair,  
17 which would be myself, William Tettelbach.

18 And that is the meeting from the 15th.

19 DR. HAMBRICK: Thank you very much.

20 Are there any questions for Dr.  
21 Tettelbach or any other members of the Data  
22 Subcommittee? Hearing none --

1 MS. DAVIS: Currently, there are no  
2 raised hands.

3 DR. HAMBRICK: Thank you. Hearing  
4 none, I'll accept a motion to accept the minutes  
5 from the Data Subcommittee.

6 DR. MANAKER: So moved.

7 DR. SETH: Second.

8 DR. HAMBRICK: Thank you. Discussion?

9 All those in favor of the motion please  
10 indicate by saying aye.

11 (Chorus of aye.)

12 DR. HAMBRICK: Opposed, nay. Any  
13 abstentions?

14 So, I know we're listed for a break,  
15 but you know we're not going to have a break  
16 now. You've been working for a half an hour.

17 So, we'll get right into the meeting.  
18 As the panel members know, we have sort of an  
19 informal-type discussion among the panel members  
20 after the presentation. So, no need to raise  
21 your hand unless, for some reason, you weren't  
22 able to get in while we were doing the

1 discussion, and then, you can raise your hand  
2 and let Ms. Davis know, so we can, you know,  
3 notice you were waiting and you didn't get a  
4 chance to speak about it.

5 So, the first presentation that we're  
6 going to have is regarding APC Assignment for  
7 Percutaneous Irreversible Electroporation  
8 Procedures. Dr. Talaga from the Division of  
9 Outpatient Care will be presenting an overview.  
10 Then, we'll have a presentation by Stuart  
11 Langbein from Hogan Lovells and Linda Upchurch  
12 from AngioDynamics.

13 If you're ready, you can go ahead, Dr.  
14 Talaga.

15 DR. TALAGA: Hi. Good morning,  
16 everyone. My name is Scott Talaga, and I will  
17 cover the CMS overview and background  
18 information for the AngioDynamics presentation.

19 AngioDynamics is requesting CMS  
20 reassign CPT placeholder codes 5XX11, 4001X, and  
21 existing CPT code 0600T to higher-paying APCs  
22 for calendar year 2026. Additionally,

1 AngioDynamics is also requesting that we use  
2 claims data from CPT code 0600T for determining  
3 the device offset percentage, the device-related  
4 portion of a procedure code, for new procedures  
5 4001X and 5XX11.

6 AMA established both CPT Code 0600T,  
7 ablation, irreversible electroporation, one or  
8 more tumors per organ, including imaging  
9 guidance, when performed percutaneous, and CPT  
10 Code 0601T, ablation, irreversible  
11 electroporation, one or more tumors per organ,  
12 including fluoroscopic and ultrasound guidance,  
13 when performed open, effective starting July  
14 1st, 2020.

15 For our calendar year 2026 OPPS ASC  
16 proposed rule, there were 327 claims that  
17 reported 0600T in calendar year 2024. The  
18 geometric mean cost of CPT code 0600T from these  
19 claims was \$13,068, and the device-related  
20 portion attributed to 57.02 percent of the  
21 geometric mean cost.

22 We propose to maintain the existing APC

1 assignment for 0600T at APC 5362, level 2  
2 laparoscopy and related services for calendar  
3 year 2026 with a proposed payment rate of  
4 \$10,966. The geometric mean cost of significant  
5 HCPCS codes within this APC ranges from \$9,008  
6 to \$13,827.

7 AMA is establishing two new CPT codes,  
8 effective January 1st, 2026, placeholder code  
9 4001X, ablation, irreversible electroporation,  
10 liver, one or more tumors, including imaging  
11 guidance, percutaneous, and 5XX11, ablation,  
12 irreversible electroporation, prostate, one or  
13 more tumors, including imaging guidance,  
14 percutaneous.

15 Additionally, with the introduction of  
16 new 4001X and 5XX11, AMA is revising CPT code  
17 0600T to specify that such code is no longer for  
18 reporting this procedure when performed on the  
19 liver or prostate.

20 Like our APC assignment of CPT code  
21 0600T, we propose to assign CPT placeholder  
22 codes 4001X and 5XX11 to APC 5362, level 2

1 laparoscopy and related services, for calendar  
2 year 2026. We assigned device-intensive status  
3 to these procedures with the default device-  
4 related portion of 31 percent.

5 While the OPPS and ASC payments both  
6 have a device-intensive policy, in the ASC  
7 setting, device-intensive procedures are paid at  
8 a higher rate. We may provide a higher default  
9 device-related portion for a new HCPCS code if  
10 the APC-wide device-related portion that the new  
11 HCPCS is assigned to is greater than 31 percent,  
12 or if there is available claims data from a  
13 predecessor code or similar code that uses the  
14 same device.

15 AngioDynamics is requesting that we use  
16 the claims data from CPT code 0600T to determine  
17 the device-related portion and increase the  
18 payout rates for 4001X and 5XX11 in the ASC  
19 setting.

20 AngioDynamics is also requesting CMS  
21 assign CPT placeholder code 5XX11 to APC 5377,  
22 level 7 urology and related services, with a

1 proposed payment rate of approximately \$13,652.

2           Additionally, AngioDynamics is  
3 requesting CMS assign CPT placeholder code 4001X  
4 and reassign CPT code 0600T from APC 5362, level  
5 2 laparoscopy and related services, to APC 1575,  
6 a new technology APC with a payment rate of  
7 \$12,500 for calendar year 2026.

8           We note that, historically, assignment  
9 to new technology APC generally occurs when  
10 there is no existing clinical APC that is  
11 appropriate in terms of clinical similarity or  
12 resources.

13           This concludes my presentation. Thank  
14 you.

15           DR. HAMBRICK: Thank you.

16           Are there any questions for Dr. Talaga?

17           If not, we'll have our presentation  
18 from Stuart Langbein and Linda Upchurch.

19           You may go ahead.

20           MR. LANGBEIN: Thanks, Dr. Hambrick.

21           Good morning.

22           And could you please go to the next



1       slide? Next slide, please.

2               My name is Stuart Langbein, and I'm  
3       with Hogan Lovells, and with me virtually is  
4       Linda Upchurch with AngioDynamics.

5               We're here in pursuit of a few  
6       recommendations pertinent to new Category I CPT  
7       codes for irreversible electroporation, or IRE,  
8       procedures, and to an existing IRE Category III  
9       CPT code 0600T, from which the other codes  
10      spring.

11              The new codes are placeholder codes  
12      4001X for a liver IRE and 5XX11 for pancreas  
13      IRE. CPT code 0600T will remain for reporting  
14      IRE procedures that involve other than the liver  
15      or pancreas.

16              So, all three codes are for the same  
17      procedure, and most of the billing of CPT code  
18      0600T in calendar year 2024 were for liver or  
19      pancreas procedures that will be reported using  
20      one of the new codes, starting in 2026.

21              We've IRE procedures in our submission,  
22      and we're happy to answer any questions about

1 the procedure, but in the interest of time,  
2 we'll go right into our requested  
3 recommendations.

4 We're asking the panel to make APC  
5 assignment recommendations on all three codes  
6 and to make recommendations on the appropriate  
7 device offset percentage for the two new  
8 placeholder codes.

9 Next slide, please.

10 First, on APC assignment, CMS proposes  
11 to assign all three procedures to APC 5362,  
12 level 2 laparoscopy and related procedures, with  
13 the geometric mean cost of \$11,137. However,  
14 the geometric mean cost for CPT code 0600T is  
15 considerably greater, \$13,068.

16 To address this lack of clinical  
17 coherence, based on the 2024 claims data, we  
18 recommend that CMS assign procedure 5XX11 to APC  
19 5377, level 7 urology and related services, with  
20 the geometric mean cost of \$13,865, and that CMS  
21 assign the liver IRE procedure 4001X and the  
22 other IRE procedure code 0600T to new technology

1 APC 1575, a range of \$10,001 to \$15,000.

2 Since we identified a clinical APC that  
3 would be clinically and more resource coherent  
4 for one of the procedures, 5XX11, we are asking  
5 you to recommend a clinical APC for that code.

6 For the other two codes, we didn't  
7 identify a clinical APC that would be a good fit  
8 on both acts. So, we recommend assignment of  
9 those codes to a new technology APC. Our  
10 requested APC recommendations for the panel to  
11 make to CMS are more reflective of what the  
12 claims data show are the resources for all three  
13 procedures.

14 Next slide, please.

15 For the device offset percentage in  
16 Addendum P for CPT code 0600T, CMS, rightly,  
17 proposes a percentage, 57.02 percent, derived  
18 from the 2024 claims data. However, for the two  
19 placeholder codes, the proposed rule, Addendum  
20 B, shows an offset percentage of 31 percent,  
21 which is the default percentage used for new  
22 codes with no claims data, but CMS policy is to

1 use claims data from a predecessor code for the  
2 device offset percentage.

3 Here, CPT code 0600T is the predecessor  
4 code for both 4001X and 5XX11. So, under CMS  
5 policy, the data from 0600T should be used to  
6 determine the device offset percentage for both  
7 4001X and 5XX11, which would be more than 25  
8 percent higher, given the proposed rule numbers.

9 Next slide, please.

10 MS. ARTIGUE: Excuse me. This is your  
11 one-minute reminder.

12 MR. LANGBEIN: Thanks.

13 In sum, here are the recommendations we  
14 ask the panel to make to CMS:

15 Assign placeholder code 5XX11 to APC  
16 5377.

17 Assign placeholder code 4001X and CPT  
18 code 0600T to APC 1575.

19 And use claims data from CPT code 0600T  
20 to compute the device offset percentage for  
21 placeholder codes 4001X and 5XX11.

22 Thank you for your consideration, and

1 we're happy to take questions.

2 DR. HAMBRICK: Thank you.

3 Does any panel member have a question  
4 for the presenter?

5 DR. MANAKER: Yes. Mr. Langbein, nice  
6 to see you again, and thanks for a good  
7 presentation.

8 I heard you talk about the similarity  
9 of resources for your request for the urology  
10 code, the prostate code, to go to APC 5377.  
11 When I take a look at 5377, the three codes  
12 there all have implantation of a device, such as  
13 a synthetic graft for the sling procedure. So,  
14 I don't see a device being inserted with the  
15 electroporation procedure. So, I don't see the  
16 clinical homogeneity with the three urologic  
17 procedures in that APC.

18 Can you or your colleague from the  
19 company help explain?

20 MS. UPCHURCH: We'd be glad to.

21 MR. LANGBEIN: Linda, do you want to  
22 talk about the device?

1 MS. UPCHURCH: Go ahead, Stuart.

2 MR. LANGBEIN: No, I was going to ask -  
3 - I was going to turn to you, Linda.

4 MS. UPCHURCH: Yeah. So, Dr. Manaker,  
5 the device has five or six probes that are  
6 inserted into the patient for the duration of  
7 the procedure. They are not a permanent  
8 placement, but they are carefully placed to be  
9 in parallel, the same distance apart, and, you  
10 know, placed into the patient for the duration  
11 of the procedure.

12 So, there is a placement of the device  
13 into the patient, just not maintained in the  
14 patient after the procedure.

15 DR. MANAKER: Yeah, right. It's not an  
16 insertion of a prosthesis, basically?

17 MS. UPCHURCH: No, it is not. It's a  
18 highly technical placement of the probes.

19 DR. DAWSON: And this is Nancy Dawson.  
20 Wouldn't that be similar with the liver  
21 procedure also?

22 MS. UPCHURCH: Yes. The actual

1 procedure is the same, just, obviously, the  
2 organ and the --

3 DR. DAWSON: Different organ.

4 MS. UPCHURCH: The vessels you're  
5 working around, the critical structures you're  
6 working around would be different.

7 MR. LANGBEIN: And I would also add to  
8 that, Dr. Manaker, that, you know, the way that  
9 APC families are structured, as you well know,  
10 they're pretty broad structures. I mean, it  
11 does fit within a level 7 urology and related  
12 services. It is a urology procedure. You know,  
13 it's not urology procedures with an implant APC.

14 So, you know, I think you could go a  
15 couple of different ways, as you're looking at,  
16 you know, what does and doesn't fit clinically  
17 within an APC family, but, you know, it seems  
18 like these are -- the family is structured  
19 pretty broadly to be urology and related  
20 services procedures, and this is.

21 And I think I mistakenly referred to  
22 pancreas instead of prostate. So, my apologies

1       for that. The lawyer creeps in sometimes.

2                   (Laughter.)

3               MR. LANGBEIN: But, you know, I do  
4 think that the way the APCs are structured, it  
5 can fit comfortably within that APC.

6               DR. MANAKER: I hear you. I just have  
7 to say, when I look at those urology procedures,  
8 they all have implantation of prosthesis or  
9 something. And when I take a look at the  
10 laparoscopy, APC 5362, I see things like partial  
11 mastectomy and other ablations, which strike me  
12 as more similar clinically to the procedure here  
13 with the electroporation, but that's just my  
14 opinion.

15              MR. LANGBEIN: No, and that's fair. I  
16 think we're trying to balance both clinical and  
17 resource coherence, and I think we feel like  
18 resource coherence is better in the recommended  
19 APCs. So, you know, I'm not going to argue with  
20 the physician over what's a better clinical fit,  
21 but I think you're balancing both clinical and  
22 resource fits in deciding on an APC, and in



1 making a recommendation to CMS. And, you know,  
2 we're putting perhaps more emphasis on the  
3 resource coherence.

4 DR. HAMBRICK: Any other questions for  
5 the presenter?

6 All right. Any questions from --  
7 anybody queued up, Ms. Davis?

8 MS. DAVIS: Currently, there are no  
9 raised hands.

10 DR. HAMBRICK: Thank you.

11 And in the chat, are there any  
12 questions in the chat?

13 MS. CESNIK: No questions in the chat.

14 DR. HAMBRICK: Thank you.

15 Would anyone from the panel like to  
16 make a motion with respect to this presentation?

17 MS. ARTIGUE: Dr. Hambrick, this is  
18 Jennifer Artigue.

19 I'd like to make a motion for one other  
20 recommendation. It makes sense to me that 0600T  
21 is the private sector code for the new procedure  
22 codes that are going to be available in January.

1       They're just creating more specific locations  
2       for CPT codes.

3               So, I would like to propose that CMS  
4       use the claims data for CPT code 0600T to  
5       determine the device offset percentage for the  
6       new codes 4001X and 5XX11.

7               DR. HAMBRICK: Is there a second?

8               DR. DAWSON: I would second that.

9               DR. HAMBRICK: Discussion on the  
10       motion?

11               Hearing none, all those in favor of the  
12       motion signify by saying aye.

13               (Chorus of aye.)

14               DR. HAMBRICK: It sounded about like  
15       four. There's about 10 of us.

16               Okay. All those opposed signify by  
17       saying nay. Hearing none -- any abstentions?  
18       Hearing none, the ayes have it.

19               Are there any other motions with  
20       respect to this presentation?

21               MS. ARTIGUE: Hey, Dr. Hambrick, I see  
22       Nicole is asking for me to repeat the codes.

1 DR. HAMBRICK: Yes, please.

2 MS. ARTIGUE: So, the request is that  
3 we use claims data for CPT code 0600T to  
4 determine the device offset for the placeholder  
5 codes 4001X and 5XX11.

6 And I'll also place them in the chat,  
7 Nicole.

8 DR. HAMBRICK: Thank you.

9 Hearing no other motions with respect  
10 to this presentation, thank you, Mr. Langbein  
11 and Ms. Upchurch.

12 MR. LANGBEIN: Thank you to the panel.

13 DR. HAMBRICK: Okay. We can get one  
14 more -- I'm sorry, I cut you off. Go ahead, Mr.  
15 Langbein.

16 MR. LANGBEIN: No, just saying thank  
17 you.

18 DR. HAMBRICK: Okay. Thank you.

19 We'll go on to the next presentation  
20 for APC Assignment of Endobronchial Valve  
21 Procedure. We'll have an overview from Ms.  
22 Tonya Gierke, and then, we'll have a public

1 presentation from Maria -- if I mess it up, Ms.  
2 Breitenfeldt, you'll let me know -- and Kelly  
3 Shriner.

4 DR. MANAKER: Dr. Hambrick?

5 DR. HAMBRICK: Yes?

6 DR. MANAKER: In keeping with my  
7 personal precedent, since this relates to my  
8 field of pulmonary and critical care medicine,  
9 I'll be recusing myself from any motions that  
10 are made. I'm happy to answer questions and  
11 provide points of information, but I won't be  
12 voting on this because it's in my specialty.

13 DR. HAMBRICK: And that's from Dr.  
14 Scott Manaker, for the record.

15 DR. MANAKER: Yes, thank you.

16 DR. HAMBRICK: Thank you.

17 Tonya Gierke, are you ready?

18 MS. GIERKE: Yes.

19 DR. HAMBRICK: Then, go ahead.

20 MS. GIERKE: All right. Hello,  
21 everyone.

22 My name is Tonya Gierke from the

1 Division of Outpatient Care. I will be  
2 providing a brief overview of Pulmonx  
3 Corporation's presentation.

4 Next slide, please.

5 CPT code 31647 is used to describe the  
6 procedure associated with the placement of an  
7 endobronchial valve in the airways of adult  
8 patients with severe emphysema. CPT code 31647  
9 is currently assigned to APC 5155, which is  
10 level 5 airway endoscopy and has a payment rate  
11 of approximately \$6,900.

12 For calendar year 2026, we propose  
13 maintaining the current payment assignments. As  
14 we will hear in the presentation from Pulmonx,  
15 they are requesting that CMS reassign CPT code  
16 31657 to a new technology APC, specifically, APC  
17 1575, with a payment of \$12,500.50, as the GMC  
18 of CPT code 31647 is approximately \$4,000 higher  
19 than the GMC of the APC it is currently placed  
20 in.

21 This concludes my overview.

22 DR. HAMBRICK: Thank you.

1                   You may go ahead with your  
2 presentation, Pulmonx.

3                   MS. BREITENFELDT: Thank you.

4                   Next slide, please.

5                   Thanks to the entire panel for giving  
6 us this opportunity to speak today.

7                   My name is Maria Breitenfeldt -- you  
8 did a great job on the pronunciation, Dr.  
9 Hambrick -- Senior Director for Health Economics  
10 and Reimbursement at Pulmonx, manufacturer of  
11 Zephyr valves.

12                  Next slide, please.

13                  Endobronchial valves are implantable  
14 valves indicated for the bronchoscopic treatment  
15 of patients with hyperinflation associated with  
16 severe emphysema. These one-way valves are  
17 intended to block air from entering the  
18 hyperinflated lobe of the diseased lung, while  
19 allowing trapped air to escape.

20                  Currently, CPT code 31647, which is  
21 used to report insertion of endobronchial  
22 valves, maps to APC 5155, level 5 airway

1 endoscopy, which is the highest-level APC of  
2 this clinical group. The geometric mean cost  
3 for CPT 31647 significantly exceeds the  
4 geometric mean cost of APC 5155. Since there's  
5 no clinically- and resource-coherent APC  
6 available in which to move it, our request is to  
7 move CPT 31647 to a new technology APC.

8 Next slide, please.

9 Let's first review what's involved with  
10 this bronchoscopic alternative to lung volume  
11 reduction surgery. The patient is anesthetized  
12 and intubated, usually in an operating room or a  
13 specially-based procedure room.

14 A bronchoscope is introduced into the  
15 lungs and navigated towards the most diseased  
16 and hyperinflated lobe. Next, a catheter is  
17 delivered to perform a physiological pulmonary  
18 assessment test, which confirms patient and lobe  
19 selection. Upon confirmation of that final  
20 assessment, a delivery catheter is introduced  
21 through the bronchoscope and used both for valve  
22 sizing and valve placement.

1                   Typically, four to five valves are  
2 needed to facilitate the collapse of the  
3 targeted hyperinflated area of the lung and  
4 expansion of the remaining healthier lung  
5 tissue, thereby improving overall lung  
6 mechanics.

7                   Finally, the patient has post-  
8 anesthesia recovery and is monitored for  
9 complications.

10                  This technology is supported by six  
11 randomized controlled trials showing that, by  
12 reducing hyperinflation, Zephyr valve treatment  
13 improves lung function, breathlessness, exercise  
14 capacity, and quality of life in patients  
15 suffering from severe emphysema.

16                  Next slide, please.

17                  With that backdrop, let's review the  
18 processes dealing with this procedure. Here are  
19 the CPT cost statistics released with the 2026  
20 proposed rule for APC 5155, where the codes are  
21 arranged from lowest to highest geometric mean  
22 cost. I've highlighted the endobronchial valve



1 procedure, 31647.

2 The data shows that 31647 has a high  
3 geometric mean cost of \$11,385, with a not  
4 insignificant number of claims. We believe,  
5 when all the 2024 data is evaluated with the  
6 upcoming final rule, this will be near 100  
7 claims.

8 The geometric mean cost for 31647  
9 represents an amount that's 57 percent above the  
10 payment rate for the APC, which translates to a  
11 loss of over \$4,000 per procedure for the  
12 hospital. This significant financial barrier  
13 restricts access for Medicare beneficiaries with  
14 severe emphysema.

15 Next slide, please.

16 It's important to note that, when we  
17 look at data from the last three years,  
18 geometric mean costs for 31647 have actually  
19 been relatively stable and always significantly  
20 exceeding the geometric mean costs of APC 5155.

21 In summary, with no clinically-relevant  
22 and resource-coherent alternative APC in which

1 to move it, we are requesting that CPT 31647 be  
2 assigned to new technology level 38 APC 1575,  
3 which has a more appropriate range from \$10,001  
4 to \$15,000.

5 This move would reflect the actual  
6 costs shown in the CMS files for the last  
7 several years and more appropriately cover costs  
8 associated with providing endobronchial valves  
9 to patients with severe emphysema.

10 Thank you for your time and attention.

11 DR. HAMBRICK: Thank you.

12 Just for the panel, and the 2X rule,  
13 31647 is on page 69, and APC 1575 would be on  
14 page 6. But, as you know, there is no procedure  
15 assigned to the new tech. There is not -- it  
16 won't appear on your 2X rule.

17 All right. Any questions for the  
18 presenters?

19 MS. ARTIGUE: Dr. Hambrick, this is  
20 Jennifer Artigue. Can I ask a question for the  
21 CMS DOC staff?

22 DR. HAMBRICK: Sure. Go ahead.

1 MS. ARTIGUE: So, my first question  
2 was, actually, about if this was a 2X rule  
3 violation.

4 Then, my second question was if they  
5 could give us a reminder of what the criteria  
6 are for inclusion in a new tech APC, since this  
7 is a preexisting code.

8 MR. RICE: Sure. Sure. I can jump in  
9 for those two.

10 So, it's not currently a 2X violation  
11 because there is enough frequency to meet the  
12 requirements for a 2X violation. So, for a code  
13 to have a 2X violation, it has to be a  
14 significant code, which means it has to have  
15 over 1,000 claims or 100 claims and 2 percent of  
16 the claims within the APC. And this code  
17 currently has 83 claims.

18 MS. ARTIGUE: Okay. Thank you.

19 MR. RICE: For the new tech APC  
20 requirement, it would be that there's not a  
21 current clinical APC that has a clinical  
22 coherence or -- and cost coherence with that

1 particular code.

2 MS. ARTIGUE: Thank you. It's helpful

3 DR. HAMBRICK: Any more questions from  
4 the panel?

5 MR. FAZIO: Yes, this is Brandon.

6 What other procedures are hospitals  
7 using in lieu of this, because of the cost  
8 issues that you are talking about, in terms of  
9 the reimbursement not being high enough? What's  
10 the alternative treatment?

11 MS. BREITENFELDT: Well, alternative  
12 treatments are lung transplant or lung volume  
13 reduction surgery. This procedure does get  
14 performed on the inpatient side as well.

15 MR. FAZIO: Okay. Thank you.

16 DR. HAMBRICK: Any other questions with  
17 respect to this presentation?

18 Is there a motion with respect to this  
19 presentation from the panel?

20 I'm sorry. Wait a minute.

21 Are there any -- is there anybody  
22 queued up, Ms. Davis? I'm sorry, I forgot.

1 MS. DAVIS: Currently, there are no  
2 raised hands.

3 DR. HAMBRICK: Thank you.

4 Anybody in the chat?

5 MS. CESNIK: No questions in the chat.

6 DR. HAMBRICK: Thank you.

7 Is there a motion with respect to this  
8 presentation, Panel Members?

9 DR. TETTELBACH: I move to --

10 DR. HAMBRICK: Okay. Hearing none --  
11 oh, I'm sorry. Who was that?

12 DR. TETTELBACH: It's Dr. Tettelbach.  
13 I was -- moved to accept the presentation.

14 DR. HAMBRICK: We need a little bit  
15 more specific motion. The fact that it's been  
16 presented is okay, but when you say, accept the  
17 presentation, we need a little bit more  
18 specificity.

19 DR. TETTELBACH: So, move to accept the  
20 proposal, as presented?

21 DR. HAMBRICK: So, you need to give us  
22 -- no, you need to give us --

1 DR. SETH: So, I'll make -- this is Dr.  
2 Seth.

3 DR. HAMBRICK: For the record, you need  
4 to -- go ahead.

5 DR. SETH: For the record, this is Dr.  
6 Seth.

7 I think what I would recommend is the  
8 panel should recommend that CMS assign CPT code  
9 31647 to APC 1575, as presented.

10 DR. HAMBRICK: Okay.

11 MR. FAZIO: I second that.

12 DR. HAMBRICK: Okay. Discussion on the  
13 motion?

14 DR. MANAKER: I second.

15 DR. HAMBRICK: No, a discussion on the  
16 motion after the second?

17 Okay. All those in favor signify by  
18 saying aye.

19 (Chorus of aye.)

20 DR. HAMBRICK: Four or five-ish.

21 Nay? And if you don't agree, please  
22 vote.

1 PARTICIPANT: Nay.

2 DR. HAMBRICK: Okay, one.

3 And any abstentions?

4 DR. MANAKER: I abstain, Dr. Hambrick.

5 It's Dr. Manaker.

6 DR. HAMBRICK: Thank you.

7 It sounds like the ayes have it.

8 I think we will take our five-minute  
9 break. But before -- because it's 10:35, right  
10 on time.

11 But before we do that, I would like to  
12 let NeuroPace know that we may move you up to  
13 before lunch, since we have three -- the  
14 presentation right after lunch has three or four  
15 presenters that I'm going to split over lunch.

16 So, NeuroPace, you might be up just  
17 before lunch. Are you available, Joel Becker  
18 and Allie D'Accurzio?

19 MS. D'ACCURZIO: Yeah.

20 DR. HAMBRICK: Okay.

21 MS. D'ACCURZIO: This is Allie. Yeah,  
22 that will work. Thank you.

1 DR. HAMBRICK: Okay. Okay. And then,  
2 I don't think we're going to get to the 1:45,  
3 Neuspera, but maybe you can be ready to, just in  
4 case. That was at 1:45.

5 All right. Let's take a five-minute  
6 break. I'll see you back here at 10:41.  
7 Thanks.

8 (Whereupon, the above-entitled matter  
9 went off the record at 10:36 a.m. and resumed at  
10 10:41 a.m.)

11 DR. HAMBRICK: All right, next up we'll  
12 have a presentation on APC Assignment for Major  
13 Depressive Disorder Treatment.

14 Tonya Gierke from the Division of  
15 Outpatient Care will provide an overview, and  
16 then Dr. Brandon Bentzley and Eric Greig will  
17 give us a presentation.

18 You may go ahead, Ms. Gierke.

19 MS. GIERKE: Hi, everyone, my name is  
20 Tonya Gierke from the Division of Outpatient  
21 Care. I will be providing the CMS overview and  
22 background information for Magnus Medical's



1 presentation. Magnus Neuromodulation System is  
2 a non-invasive repetitive transcranial magnetic  
3 stimulation system that identifies an  
4 individualized target located within the left  
5 dorsolateral prefrontal cortex and delivers  
6 repetitive magnetic pulses to that target  
7 treating Major Depressive Disorder. Next slide,  
8 please.

9 The AMA CPT Editorial Panel created  
10 four new CPT Category 3 codes, 0889T, 0890T,  
11 0891T, and 0892T, effective July 1, 2024, to  
12 describe this therapy. These codes were  
13 assigned to New Technology APCs. The codes,  
14 along with their descriptors, are listed on this  
15 slide. Next slide, please.

16 As we will hear in the presentation for  
17 Magnus Medical, they are requesting that CMS  
18 maintain the current APC assignments for the  
19 three CPT codes that describe the repetitive  
20 transcranial magnetic stimulation treatment,  
21 specifically 0890T, 0891T, and 0892T, to better  
22 align with the cost of this therapy.

1 Magnus Medical asserts that the cost  
2 for providing this five-day treatment is  
3 approximately \$18,400. For calendar year 2026,  
4 we identified fewer than 100 claims for CPT code  
5 0890T and 0891T. As this is below the threshold  
6 of 100 claims for a service within a year, we  
7 propose to apply our universal low-volume APC  
8 policy and use the highest of the geometric mean  
9 cost, arithmetic mean cost, or median cost based  
10 on up to four years of claim data to assign  
11 these CPT codes to the appropriate New  
12 Technology APC.

13 As a reminder, New Technology APCs are  
14 designated by cost bands, which allow us to  
15 provide appropriate and consistent payment for  
16 designated new procedures that are not yet  
17 reflected in our claims data. We return a -- we  
18 retain a service within a New Technology APC  
19 until we acquire sufficient data to assign it to  
20 a clinically appropriate APC group. And this  
21 concludes my overview.

22 DR. HAMBRICK: Thank you. Any panel

1 members have a question for Ms. Gierke?

2 If not, you may go ahead, Magnus

3 Medical.

4 DR. BENTZLEY: Thank you so much. Next

5 slide, please. My name is Brandon Bentzley, I

6 am a psychiatrist, as well as the co-founder and

7 Chief Scientific Officer for Magnus Medical, and

8 today I will be discussing the SAINT

9 Neuromodulation Therapy. Next slide.

10 As a reminder, the SAINT is a form of

11 Transcranial Magnetic Stimulation, it means non-

12 invasive neurostimulation that's targeted using

13 structural and functional magnetic resonance

14 imaging. Very uniquely, depression treatments

15 typically take weeks to months or even longer to

16 work; for SAINT, the treatment lasts, actually,

17 only five days, with a mean time to remission

18 from depression of only 2.6 days, making it the

19 most rapid acting form of neuromodulation for

20 depression.

21 There are three steps to providing the

22 treatment. First, the patient receives a

1 functional and structural magnetic resonance  
2 imaging scan, that data are sent to our  
3 processing. It takes about a half-day of  
4 processing to identify a full set of brain maps  
5 and select a target that will be stimulated.

6 The patient then undergoes a five-day  
7 treatment protocol. It's a very intensive  
8 treatment protocol in which the patient receives  
9 ten minutes of neurostimulation every hour for  
10 ten hours each day, across five days. A  
11 neuronavigation system, which is a frameless  
12 stereotactic system, now using 3D cameras, is  
13 used to ensure that the coil stays in the right  
14 location and requires a physician and a  
15 technician. Next slide.

16 From the last time that I had the  
17 opportunity to speak to this committee, we've  
18 increased the amount of patients who have run  
19 through our clinical trials. As a review of the  
20 clinical data that was used for FDA clearance --  
21 it was from two open-label clinical trials, as  
22 well as a randomized control trial -- in our

1 randomized control trial, we found a 79 percent  
2 remission rate in SAINT compared to a 13 percent  
3 remission rate in the sham treatment.

4 And in comparison to other typical  
5 treatments that would be alternatives in this  
6 group, while we would typically see  
7 pharmacotherapy, and in this particular group  
8 who have already failed pharmacotherapy, there's  
9 a very low rate of remission of only 14 percent.  
10 Or, for Conventional Transcranial Magnetic  
11 Stimulation, which is not MRI guided and only  
12 given once a day for 36 days, similarly, only  
13 about a 14 percent remission rate. We had  
14 actually just wrapped up a real-world clinical  
15 trial of 108 participants, which reflects the  
16 same data. Next slide.

17 Before I hand it off to my colleague,  
18 one of the other, you know, differences is we,  
19 really, just brought this to market in mid-2024  
20 and we finally, actually, are able to see real-  
21 world experience and reports from our physicians  
22 on what it's like to actually provide this

1 service, which is, you know, very new for the  
2 world of psychiatry.

3 The patients are very severe and they  
4 typically have, you know, suicidality and  
5 they're in the middle of crisis, which is why  
6 they are able to, really, qualify for getting  
7 such an intense five-day treatment, and requires  
8 a lot of hands-on, you know, complete engagement  
9 of the clinical team throughout the ten hours  
10 that the patient is at the clinic for each of  
11 the five days.

12 And I'll hand it off to my colleague,  
13 Eric.

14 MR. GREIG: Thank you, Brandon. The  
15 one other point I would make on this slide is  
16 that, among the three treatment procedures that  
17 are under evaluation here, there's no material  
18 difference in the hospital costs among those  
19 treatment days. There's a motor threshold  
20 procedure that's performed that takes different  
21 physician work, but the hospital resources, as  
22 summarized here and as mentioned by Tonya, are

1       consistent. Next slide, please.

2               So this slide recaps the information  
3       that CMS presented. As you could see, the  
4       effect that this proposed APC reassignment would  
5       have a reduction of 40 to 50 percent in hospital  
6       reimbursement year-over-year, based on,  
7       effectively, six months of claims data for the  
8       initial launch. So, that would create very  
9       serious barriers to access for this treatment,  
10      given the year-over-year reduction.

11              MS. ARTIGUE: Pardon me. One minute  
12      reminder, please.

13              MR. GREIG: Thank you. On the next  
14      slide, we can go into, sort of, exactly what  
15      happened based on our review of the claims data.  
16      And as far as we can see, in those first six  
17      months, there were only two hospitals that began  
18      SAINT treatment in 2024, and one hospital just  
19      simply had challenges with where these costs  
20      were reported and how they translated into the  
21      claims data.

22              For less than seven patients, Provider

1       2 had reported costs of less than \$500. They've  
2       acknowledged this was an error and that the  
3       revenue code assignment was mistakenly, but  
4       automatically, assigned, which resulted in this  
5       great variability in reported costs.

6               And so, what we're requesting on the  
7       next slide is that, given this variability, the  
8       novelty of the procedure, that CMS maintain the  
9       New Tech APC assignment for all three procedures  
10      at the same rate as for 2025, which they  
11      developed through the rulemaking process and  
12      through the New Technology APC authorization  
13      process. Thank you very much.

14             DR. HAMBRICK: Thank you. Are there  
15      any questions for the presenters?

16             DR. DAWSON: Yeah, I have a question --  
17      (Simultaneous speaking.)

18             DR. HAMBRICK: From the panelists.

19             DR. DAWSON: I have a question. Can  
20      you give us just a little more detail about the  
21      error from Provider 2, what happened there?

22             MR. GREIG: Sure --



1 DR. DAWSON: That's a huge discrepancy.

2 MR. GREIG: It really is. And as we  
3 understand it, the revenue code assignment was  
4 automatically included from the revenue cycle,  
5 without the input of the clinical team or  
6 further understanding of the procedure. And if  
7 you go back to that prior chart, you can see the  
8 CCR is less than 20 percent of what we see for  
9 the appropriate revenue code assigned from  
10 Provider 1.

11 So, what we've understood in  
12 conversations with that hospital is that this  
13 was just automatically assigned in the backup  
14 office, and they're correcting the issue, but,  
15 because these are 2024 claims, there's not much  
16 they can do otherwise. They're aware of it now,  
17 they're making a change, but that's what  
18 occurred in those -- and again, we're talking  
19 about less than ten patients in 2024 within the  
20 first six months of launch.

21 DR. DAWSON: Okay, thank you.

22 DR. HAMBRICK: Did you have a follow-

1 up, Dr. Dawson?

2 DR. DAWSON: I'm sorry, what --

3 (Simultaneous speaking.)

4 DR. HAMBRICK: Dr. Manaker -- I was  
5 asking, did you have a follow-up?

6 DR. DAWSON: No, thank you.

7 DR. HAMBRICK: Dr. Manaker?

8 DR. MANAKER: Thank you. I just have a  
9 quick question about the second hospital here.  
10 Was there any consideration of having someone  
11 from their finance department join you today for  
12 the presentation? Here at the panel, we have  
13 had errors like this happen and, at least  
14 previously, somebody from that institution would  
15 do exactly as you describe, say we made a  
16 mistake, we had the wrong revenue code, we're  
17 amending the cost reports, rather than you  
18 speaking on their behalf.

19 MR. GREIG: Understood.

20 DR. MANAKER: Is there any --

21 MR. GREIG: Yeah, Dr. Manaker, I think  
22 in the time given, the limited time here, we

1 wanted to make sure that we could summarize  
2 this. We will have that provider presenting to  
3 CMS this week, as well as submitting comments to  
4 this effect.

5 I think the -- overall, the high  
6 variability in these reported costs and the  
7 circumstances, we believe, support the continued  
8 assignment. You know, just -- the data sort of  
9 speaks for itself a little bit, when you have a  
10 ten-hour procedure that is reported at less than  
11 \$500 for the hospital, I think that it's hard to  
12 be anything other than an error, given the  
13 investment.

14 But I hear you, and I think it was just  
15 more of an unfamiliarity with the process and  
16 the limited time to present here.

17 DR. MANAKER: Thank you.

18 DR. HAMBRICK: Anymore questions from  
19 the panel? Is there anybody in queue, Ms.  
20 Davis?

21 MS. DAVIS: Currently, there are no  
22 raised hands.

1 DR. HAMBRICK: Thank you. Anybody in  
2 chat?

3 Okay, is there a motion with respect to  
4 this presentation?

5 DR. MANAKER: Yes, on the presumption  
6 that someone from Hospital Number 2 will present  
7 to CMS later this week and acknowledge the  
8 error, I would move that we maintain 0890T,  
9 0891T, and 0892T in New Tech APC 1525.

10 DR. SETH: I will second that motion.  
11 Thank you, Scott.

12 DR. HAMBRICK: Discussion?

13 All those in favor, signify by saying  
14 aye.

15 (Chorus of aye.)

16 DR. HAMBRICK: Opposed? Any  
17 abstentions? Thank you, the ayes have it.  
18 Thank you very much for your presentation.

19 MR. GREIG: Thank you.

20 DR. HAMBRICK: We will now move --  
21 thank you -- to the APC Assignment and Status  
22 Indicator for Peripheral Nerve Stimulation

1       Therapy. We'll have a presentation from Gil  
2       Ngan from the Division of Outpatient Care, and  
3       from Neuralace we'll have a presentation from  
4       Evelyn Gittinger, Marshall Bedder, and Joe  
5       Milkovits, there we go. You're reminded, five  
6       minutes. If you want to go ahead, Mr. Ngan.

7               MR. NGAN: Thank you, Dr. Hambrick.  
8       Hi, I'm Gil Ngan from the Division of Outpatient  
9       Care. I will cover the CMS overview and  
10      background information on Neuralace Medical's  
11      presentation on Axon Therapy.

12             CPT codes 0766T and 0767T became  
13      effective January 2023. The descriptor for CPT  
14      code 0766T is Transcutaneous magnetic  
15      stimulation by focused low-frequency  
16      electromagnetic pulse, peripheral nerve, with  
17      identification and marking of the treatment  
18      location, including noninvasive  
19      electroneurographic localization, nerve  
20      conduction localization, when performed, first  
21      nerve.

22             The descriptor for 0767T is

1 Transcutaneous magnetic stimulation by focused  
2 low-frequency electromagnetic pulse, peripheral  
3 nerve, with identification and marking of the  
4 treatment location, including noninvasive  
5 electroneurographic localization, nerve  
6 conduction localization, when performed; each  
7 additional nerve, list separately in addition to  
8 code for primary procedure.

9 HCPCS code 0766T became effective  
10 January 1, 2023, and was assigned to APC 5721  
11 Level 1 Diagnostic Tests and Related Services,  
12 with a status indicator Q1, initially packaged.

13 For CY2025, we finalized the  
14 reassignment of HCPCS code 0766T to APC 5722  
15 Level 2 Diagnostic Tests and Related Services,  
16 with a proposed treatment rate of approximately  
17 \$311 and reassigned status indicator to S,  
18 separate APC payment.

19 For CY2026, the proposed OPPS payment  
20 rates are based on available CY2024 claims data.  
21 We note that we did not receive any claims data  
22 for CY -- for HCPCS 0766T in 2023 or 2024. We

1       note that CPT code 0767T with a status indicator  
2       N is packaged. It is our longstanding OPPS  
3       packaging policy that payment for add-on codes  
4       is generally packaged into the primary  
5       procedure.

6               We have stated in prior final rules  
7       that procedures described by add-on codes that  
8       present an extension or continuation of a  
9       primary procedure, which means they are  
10      ancillary, supportive, dependent, or adjunctive  
11      to a primary service. Add-on codes describe  
12      services that are always performed in addition  
13      to a primary procedure; they are never reported  
14      as a standalone code.

15             Given the dependent nature and  
16      adjunctive characteristics of procedures  
17      described by add-on codes, payment for add-on  
18      codes is generally packaged into the primary  
19      procedure.

20             Next, you will hear a representation  
21      from Neuralace Medical requesting the  
22      reassignment of CPT codes 0766T and 0767T to a

1 different, higher-paying APC, and requesting to  
2 change the proposed status indicators for these  
3 codes.

4 This concludes my presentation, thank  
5 you.

6 DR. HAMBRICK: Thank you. For the two  
7 times rule, 0766T is on page 178, and APC 5431  
8 is on page 131. You may go ahead, Neuralace.

9 MS. GITTINGER: Good morning, Panel.  
10 My name is Evelyn Gittinger and I am the  
11 consultant to Neuralace. Joining me, also, on  
12 this call is Dr. Marshall Bedder the CMO and Joe  
13 Milkovits who is the President and CEO. Thank  
14 you very much to the Panel for your time and the  
15 opportunity to present. Next slide, please. Go  
16 ahead, next slide.

17 What we -- our request is similar to  
18 what we did last year, we met with the panel,  
19 and we're requesting that the panel recommend to  
20 CMS reassignment of 07 -- CPT 0766T and 0767T,  
21 primarily to APC 5431 Level 1 Nerve Procedure.

22 This was the recommendation made last



1 year to the Panel -- or, excuse me, by the  
2 Panel, to CMS, and, unfortunately, it was not  
3 elevated to that, it was elevated to 5722. And  
4 given the price change, now, that's going into  
5 coverage year 2026, there's even more of a  
6 barrier.

7 We are also asking for CMS to, again,  
8 change the status indicator for CPT 0767T to S  
9 and not have it packaged. Next slide, please.

10 We are presenting two different  
11 options for the Panel to consider. The primary  
12 option of the 5431 for the Level 1 Nerve, as  
13 well as a secondary option, if we need to stay  
14 in the status of diagnostic and related  
15 services, we are presenting an alternative APC.

16 And again, as I reiterated, there is a  
17 financial access barrier for Medicare to use  
18 this service. Next slide, please.

19 I'm going to turn this over to my  
20 colleague, Dr. Bedder, who can discuss and  
21 provide you a presentation on the technology  
22 itself.

1                   MR. BEDDER: Great. Thank you for  
2                   having us. So Axon Therapy is a magnetic  
3                   peripheral nerve stimulation device. It's FDA  
4                   cleared to stimulate peripheral nerves for  
5                   relief of chronic intractable pain, post  
6                   traumatic, post-surgical pain, and for relief of  
7                   chronic painful diabetic peripheral neuropathy  
8                   in the lower extremities.

9                   So it's really the first 100 percent  
10                  non-invasive electroceutical platform cleared by  
11                  the FDA for treatment of painful diabetic  
12                  neuropathies, which is a very tough diagnosis to  
13                  treat.

14                 And this uses a magnetic pulse, not an  
15                 electrical one. So it engages the sensory and  
16                 motor fibers in a mechanistic manner to  
17                 recondition the central nervous system by  
18                 eliminating the noxious pain signals to the  
19                 pain.

20                 It also has some direct effects on the  
21                 brain by re-plasticity and reconditioning. The  
22                 pain respondent's rate goes up to 87 percent in

1 responders, anything greater than 50 percent or  
2 more.

3 After a single treatment, we see  
4 patients showing about a 54 percent decrease in  
5 pain. And after three treatments, on average,  
6 72 percent decrease in their actual pain scores.  
7 You can, you know, after one or two treatments,  
8 you know if you have a responder or not.

9 So this is truly a breakthrough device  
10 for chronic neuropathic pain management. It can  
11 help decrease dependence on opioids. I also run  
12 the Addition Medicine Fellowship program. And  
13 we're able to reduce opioid utilization on our  
14 first study by 51 percent.

15 The general treatment protocol is about  
16 five to six treatments in the first month. And  
17 then it goes once per month until it, usually  
18 patients will basically improve enough that they  
19 don't need to keep coming back, and come back on  
20 a PRN basis. Thank you.

21 MS. GITTINGER: Next slide, please.  
22 Here, it's a slide to support. This slide is

1 very similar to what we presented last year in  
2 our request for APC 5431 Level 1 nerve  
3 procedure, our procedure, as you will see in our  
4 second bullet there.

5 We are a therapeutic procedure to the  
6 nerve itself that requires identification and  
7 mapping of the nerve. And then performing the  
8 actual treatment once that nerve is identified.

9 And secondarily on that, where we want  
10 to, want everyone to understand, a second nerve,  
11 we have to go through additional mapping on that  
12 second nerve.

13 And often when you're dealing with  
14 diabetic peripheral neuropathy there are second  
15 nerve, bilateral nerves involved.

16 This procedure we have an estimated  
17 facility cost of \$1,500. And if we look at the  
18 geometric mean \$2,031. And then the coverage  
19 here proposed rate of \$1,999. That would  
20 actually align with this particular composite  
21 APC.

22 MS. ARTIGUE: Excuse me. This is your

1       one minute reminder.

2               MS. GITTINGER: Thank you. Next slide,  
3       please.

4               MR. BEDDER: Okay. So the alternative  
5       recommendation, APC 5724. So IB STIM, which is  
6       an irritable bowel stimulation device, compared  
7       to ours.

8               They are in the 5724 Level 4  
9       diagnostic. And we're in the 5722 Level 2. And  
10      theirs is for relief of abdominal pain. Ours is  
11      for, as I told you, the chronic contractile  
12      neuropathic pain.

13              Well they stimulate peripheral nerves  
14      cranial. We do peripheral nerves. They're  
15      electrical. We're electromagnetic. They're a  
16      battery operated small device that has a set way  
17      to apply it.

18              There's a template. You just put it on  
19      the ear and that's it. Ours requires mapping,  
20      physician knowledge of nerves. And is very  
21      similar to if you were doing a nerve block  
22      actually.

1                   They have four little small needle  
2                   arrays with their battery operated machine. We  
3                   have a large magnetic generator that goes up to  
4                   1.6 Tesla, and a wand arm that is then used for  
5                   the mapping.

6                   So a significant increase in the  
7                   technology, and in the time spent and expertise  
8                   needed to perform. Thank you.

9                   MS. GITTINGER: Next slide, please.  
10                  And in summary, we just want to reiterate that  
11                  we really hope that you will make the  
12                  recommendation again to CMS to follow as last  
13                  year, to place us in APC 5431 for both CPT 0766T  
14                  and 0767T.

15                  If the alternative, and they choose to  
16                  keep us in the diagnostic and related services  
17                  family, then we are requesting to be elevated to  
18                  APC 5724, as well as in that case changing our  
19                  status indicator for both to Status Indicator S  
20                  40766T and 0767T.

21                  That concludes, and we really  
22                  appreciate your time. And we are happy to take

1       any questions. Thank you.

2               DR. HAMBRICK: Thank you. Are there  
3       any questions from the panel for the presenters?

4               MS. ARTIGUE: Hi, Dr. Hambrick. This  
5       is Jennifer. I do have a question for the  
6       presenters.

7               DR. HAMBRICK: Okay.

8               MS. ARTIGUE: Do the --

9               DR. HAMBRICK: Go ahead, please.

10              MS. ARTIGUE: Yes. My background is  
11       not clinical. But I do understand the concerns  
12       with the codes being in a diagnostic APC, rather  
13       than a therapeutic one.

14              But I do have a question in the request  
15       for the status indicator change. Can you help  
16       me understand? I know you talked about mapping,  
17       what the increased resource consumption would be  
18       to have an additional nerve evaluated?

19              MR. BEDDER: Sure. Well --

20              MS. ARTIGUE: Plus reading.

21              MR. BEDDER: In a diabetic neuropathic  
22       patient. So if we're going to treat the lower

1       extremity, we'd go, if they're laying down right  
2       behind your knee, we call it the popliteal  
3       fossa. It's where the sciatic nerve splits.

4               And so you've got to actually place the  
5       wand, and move the wand while working with the  
6       patient as you gradually increase the power to  
7       get a motor response, certainly, but a sensory  
8       response, what we call a paresthesia.

9               And it's going to be different. You've  
10      got to go from one nerve on one leg, over to the  
11      other leg. And do that all over for a different  
12      leg, which may be slightly different  
13      anatomically. It takes twice the amount of  
14      time. That --

15              MS. ARTIGUE: Okay. Okay. That makes  
16      sense. Thank you.

17              MR. BEDDER: Okay, great.

18              DR. HAMBRICK: I believe Mr. Fazio had  
19      a question in the chat. Did you have a  
20      question?

21              MR. FAZIO: Yes, I did. Just what's  
22      the average length of time for the procedure for



1       each patient?

2               MR. BEDDER:   Sure.   It will vary, of  
3       course, for different diagnoses.   Because it may  
4       be more technically difficult getting exposure  
5       where we want.

6               But in general, we allow half an hour.  
7       And that involves bringing the patient in,  
8       consenting, getting them positioned, getting the  
9       machine over, mapping, and then administering  
10      the actual therapy to them.   So I'd say about a  
11      half hour.

12              MR. FAZIO:   Thank you.

13              MR. BEDDER:   You're welcome.

14              DR. HAMBRICK:   Dr. Manaker.

15              DR. MANAKER:   Well, thank you.   So I've  
16      got a couple of quick questions.   The first one  
17      is, what is the underlying procedure that this  
18      is typically done with?

19              MR. BEDDER:   You mean the diagnoses  
20      that we would treat, sir?

21              DR. MANAKER:   Well, if it's, if  
22      something else is being done, and it's being

1 packaged into that something else. Can you tell  
2 me what that something else usually is? Is it  
3 EMG --

4 MR. BEDDER: No.

5 DR. MANAKER: -- neuroconduction  
6 velocities? What --

7 MR. BEDDER: At this point, we're doing  
8 the treatment. We're not doing any nerve  
9 conduction aspects. There is a patent that the  
10 company holds for future utilization of that.

11 But the actual treatment itself is what  
12 I just described in administering 400 pulses  
13 total to the patient. The actual something else  
14 you're talking about is the mapping part.

15 Because without getting, you know,  
16 appropriate paresthesia telling you you're on  
17 the nerve, femoral nerve, suprascapular nerve,  
18 median nerve, femoral nerve, sciatic nerve, then  
19 you wouldn't be getting the effect.

20 So one has to have an anatomic basis,  
21 have some specialty training to understand what  
22 we're doing. So there is, you know, the many

1 specialties, anesthesia, PMNR, and neurology.  
2 They can, they all very easily can do this.

3 DR. MANAKER: But there's a separate  
4 CPT code built for finding that nerve to then  
5 provide the pulses, correct?

6 MS. GITTINGER: It's all one CPT code.  
7 It's built in --

8 (Simultaneous speaking.)

9 DR. MANAKER: -- all been built in.

10 MS. GITTINGER: It is. And then that  
11 add-on, what the confusion I think is, if it's  
12 the same procedure, but it's to an additional  
13 nerve. And that's how it was structured at CPT.

14 DR. MANAKER: Okay. And then my other  
15 question is, when I look at the APC 5431 it's  
16 largely surgical procedures, incisions,  
17 ablations, destructions, et cetera.

18 So, you know, I don't see the clinical  
19 coherence with that APC. I could be convinced  
20 that it should remain in the 5724, you know,  
21 category. But I don't see it going into 5431.  
22 Because there's no clinical coherence there.

1                   MR. BEDDER: Well, I think the clinical  
2 coherence was that, as an anesthesiologist  
3 background it is very similar to what we would  
4 do for nerve block procedures. Isolating and  
5 then treating the nerve.

6                   And so that's the correlation. It is  
7 not diagnosing anything at all. And it is a  
8 treatment, and a very effective treatment, up to  
9 94 percent in the last study of responders, for  
10 neuropathic pain.

11                  So we're doing more than a nerve block  
12 does. And that's the rationale. From an  
13 anesthesia point of view, it correlates.

14                  DR. MANAKER: Yes. But from an  
15 anesthesia point of view, I could see that. But  
16 I'm just taking a look at the CPT codes that are  
17 in APC 5431. And it's destruction of joints,  
18 and destruction of nerves. It's not a non-  
19 invasive transcutaneous therapeutic. So that's  
20 why I don't see this going into 5431. I could  
21 see it going into the 5724.

22                  MS. GITTINGER: And, Dr. Manaker,

1       that's why we offered that alternative. We, for  
2       us, the procedure to us in trying to discover  
3       this wasn't a diagnostic, as Dr. Bedder was  
4       saying.

5               And we felt that, clinically, it was a  
6       nerve procedure. We're trying to treat a nerve.  
7       We're not trying to diagnose or have a related.  
8       But that's why we offered that alternative.

9               And we use that, the IB Stim as  
10       somewhat of an analogue. Because we are much  
11       greater in terms of what was required. And that  
12       particular code was placed into the higher level  
13       APC.

14              And in that sense, too, that's where we  
15       felt changing it, if we had to stay in there,  
16       along with changing our status indicator, we  
17       could understand if that was the position that  
18       the panel took, as well as CMS. We believe that  
19       if we have to stay in that family to elevate us  
20       to a more appropriate APC level.

21              DR. MANAKER: Well, when I take a look  
22       at 5724, it's mainly diagnostic tests. But

1       there are some therapies like electroconvulsive  
2       therapy. So again, I could be convinced for  
3       5724. Thank you.

4               DR. HAMBRICK: Thank you. Any other  
5       panel members have questions? Ms. Artigue, are  
6       you coming off mute?

7               MS. ARTIGUE: No, ma'am.

8               DR. HAMBRICK: Okay. Ms. Davis, is  
9       anybody in queue?

10              MS. DAVIS: No, ma'am. There are no  
11       raised hands at this time.

12              DR. HAMBRICK: Thank you. Anybody in  
13       the chat for questions?

14              MS. CESNIK: No questions in the chat.

15              DR. HAMBRICK: Thank you. Is there a  
16       recommendation from the panel with respect to  
17       this presentation?

18              DR. MANAKER: I'll move to recommend it  
19       be placed in APC 5724.

20              DR. SETH: I'll second that.

21              DR. HAMBRICK: Okay. Discussion? All  
22       those in favor of the motion, please indicate by

1 saying aye.

2 (Chorus of aye.)

3 DR. HAMBRICK: Opposed? Any  
4 abstentions? Thank you very much.

5 MR. DIRKSEN: Sorry to interrupt. We  
6 need to address the --

7 DR. HAMBRICK: Yes. Yes. I'm sorry.  
8 Another --

9 (Simultaneous speaking.)

10 MS. ARTIGUE: Yes. I'd like to make  
11 another proposal.

12 DR. HAMBRICK: Sorry. Go ahead.

13 MS. ARTIGUE: That's okay. Given the -  
14 -

15 DR. HAMBRICK: And I can see Mr.  
16 Dirksen.

17 MS. ARTIGUE: Given the increased  
18 resource consumption described by the presenter,  
19 I would like to propose that CMS change the  
20 status indicator for HCPCS Code 0767T from  
21 status indicator N to status indicator F.

22 DR. HAMBRICK: Is there a second?

1 MR. DIRKSEN: I second.

2 DR. HAMBRICK: Okay. Mr. Dirksen, did  
3 you have a comment previously on the last  
4 motion?

5 MR. DIRKSEN: No. I just wanted to  
6 make sure we addressed the status indicator.

7 DR. HAMBRICK: Thank you. Ms. Trevas,  
8 go ahead, please.

9 MS. TREVAS: Thank you. Can you hear  
10 me?

11 DR. HAMBRICK: Yes, we can.

12 MS. TREVAS: Yes. Great. Okay. So,  
13 on the first recommendation from Dr. Manaker,  
14 you are recommending that both of the codes be  
15 moved into 5724. Is that correct?

16 DR. MANAKER: Yes.

17 MS. TREVAS: Okay. And then for Ms.  
18 Artigue, the request is for 0767T to change the  
19 status indicator from N to S. Is that correct?

20 MS. ARTIGUE: Yes. That's correct,  
21 Dana. Thank you.

22 MS. TREVAS: Thank you very much.



1 DR. HAMBRICK: Was there a second to  
2 the motion? Sorry.

3 DR. TETTELBACH: I second.

4 DR. HAMBRICK: Ms. Artigue. Thank you.  
5 Discussion? Hearing none, all those in favor  
6 signify by saying aye.

7 (Chorus of aye.)

8 DR. HAMBRICK: Opposed, nay. Any  
9 abstentions? The motion carries. Okay. Thank  
10 you very much --

11 MS. GITTINGER: Thank you.

12 DR. HAMBRICK: -- Neuralace. Next,  
13 we're going to go on to a presentation about APC  
14 Assignment for Laparoscopic Procedures. Ngan  
15 gets to say because he likes it so much. And  
16 we're going to have a presentation from Roberta  
17 Guthery from Intuitive Surgical. And go ahead  
18 Mr. Ngan.

19 MR. NGAN: Thank you, Dr. Hambrick.  
20 I'm coming at it from the position about patient  
21 care, and will cover the CMS public view and  
22 background information, an Intuitive

1 presentation on three laparoscopic procedures.

2 APC Codes 49650, 49651, and 44970  
3 became effective in January 2000. A descriptor  
4 for CPT Code 49650 as laparoscopy surgical  
5 repair initial inguinal hernia.

6 The descriptor for 49651 is laparoscopy  
7 surgical repair of recurrent inguinal hernia.

8 The descriptor for CPT Code 44970 is laparoscopy  
9 surgical appendectomy.

10 For CY 2025, CPT codes 49650, 49651,  
11 and 44970 were assigned to APC 5361, Level 1  
12 laparoscopy and related services, with a status  
13 indicator of J1, comprehensive APC, with a  
14 proposed payment rate of approximately \$5,834.

15 For CY 2026, the proposed OPPS payment  
16 rates are based on available CY 2024 claims  
17 data. We know that CPT Code 49650 received over  
18 44,000 claims with a geometric mean cost of  
19 \$7,050.

20 And CPT Code 49651 received 4,620  
21 claims with a geometric mean cost of \$7,173 in  
22 2024. CPT Code 44970 received 9,631 claims and

1 had a geometric mean cost of \$6,778 in 2024.

2 We know that for CY 2026, we propose to  
3 maintain CPT Codes 49650, 49651, and 44970, and  
4 APC 5361, Level 1, laparoscopy and related  
5 services, because of the resource and clinical  
6 similarity to other services in this APC.

7 We know that CPT Codes 44970 and 49650  
8 qualify for the complexity adjustment when  
9 reported together. Therefore, when the pair  
10 combination CPT Codes 44970 and 49650 are  
11 reported on the same claim, the payment rate is  
12 promoted to the next higher cost CAPC, which is  
13 APC 5362.

14 Next, you will hear a presentation from  
15 Intuitive Surgical requesting the reassignment  
16 of CPT Codes 49650, 49651, and 44970 to a  
17 different higher APC, APC 5342, Level 2  
18 Abdominal Perineal Biliary and related  
19 procedures.

20 This concludes my presentation. Thank  
21 you.

22 DR. HAMBRICK: Thank you. Any

1        questions for Mr. Ngan? If not, go right ahead,  
2        Ms. Guthery.

3                MS. GUTHERY: Thank you. And thank  
4        you, Gil, and to the panel for giving us a few  
5        minutes today to provide an overview and the  
6        reason for the request for the change.

7                You can go ahead to the next slide,  
8        please. Next slide, please. We're just going  
9        to jump right into it. You can advance the  
10       slide. There you go.

11               Just a level set with the panel. Open  
12       surgery is just as we call it here. It's an  
13       open incision. You can visually see the wound  
14       and perform the operation.

15               If you advance the slide, please you  
16       can see that the laparoscopic surgery is, it's  
17       inflating the belly and putting those  
18       instrumentations through the small ports to be  
19       able to perform procedures while viewing the  
20       patient's anatomy on a screen.

21               Advance the slide again, please.  
22       Robotic-assisted surgery is essentially a

1 laparoscopic surgery that's being assisted by a  
2 robot.

3           So those same tools and instrumentation  
4 are being put into the inflated belly, but  
5 connected to the arms of a robot, where there is  
6 better articulation, and really good  
7 visualization for the surgeon when they perform  
8 the procedure.

9           Next slide, please. This is why, back  
10 in 2007, the AMA made the decision not to create  
11 a separate code set for robotic-assisted  
12 surgeries, procedures in a soft tissue space.

13           So, we even see new and updated codes  
14 that now include robotic assistance when  
15 performed in the description to eliminate any  
16 confusion. Just like what we saw with  
17 laparoscopic surgical prostatectomy a few years  
18 back, when it was a brand new CPT code.

19           Fast forward to 2023, our friends at  
20 the AMA updated and created 12 brand new  
21 procedure codes for abdominal hernia repair.  
22 First in kind in the soft tissue surgery space,

1 they included open, lap, and robotic approaches  
2 in the same description.

3 So it doesn't matter what approach  
4 you're using, you're going to use that same CPT  
5 code, or the same, correct, same CPT code. So  
6 the key takeaway here is, up to this point, CMS  
7 had always assigned procedures based on surgical  
8 approach.

9 So there are APCs for open approach,  
10 and there are APCs for laparoscopic approach, as  
11 Gil outlined for us. So they were left with a  
12 conundrum of assigning these 12 new procedures  
13 to APCs that were available.

14 And they wound up, based on  
15 historically looking back at geometric mean  
16 costs associated with the former codes,  
17 splitting it up between the two APCs they had  
18 available, 5341 and 5361, which eliminated that  
19 separation based on surgical approach. Because  
20 now, you have all three approaches in each of  
21 the descriptions.

22 Next slide, please. In 2024, it became

1       very clear, based on geometric mean costs for  
2       the claims that were being submitted, that there  
3       was a need to create a new Level 2 abdominal  
4       procedure APC.

5               And so to begin to acquire, to begin to  
6       make room for these, the geometric mean costs  
7       associated with all of these new hernia  
8       procedures.

9               So here we are in 2025. We have a  
10       mixture of open and lap procedures in APC 5361.  
11       Open, lap, and robotic in 5341. And open, lap,  
12       and robotic in 5342.

13              Next slide, please. Which brings us to  
14       our request today. And that is to, in APC 5342,  
15       we currently have open, initial, and recurrent  
16       inguinal hernia repair, and open appendectomy  
17       assigned to APC 5342.

18              We're asking CMS from a clinical  
19       similarity, a resource utilization standpoint,  
20       to assign the laparoscopic counterparts to the  
21       same APC 5342.

22              So 49650 and 651 is the lap approach.

1       Going from 5361 over to 5342, the post-payment  
2       rate of \$6,667 for 2026. And then the same for  
3       open appendectomy that you see down here at the  
4       bottom.

5               We would propose that you include the  
6       laparoscopic approach in the same APC as the  
7       open, so they would all be together from a  
8       clinical similarity and resource utilization in  
9       the same APC. Next slide --

10              MS. ARTIGUE: One-minute reminder.

11              MS. GUTHERY: Thank you. The impact of  
12       making that change, I thank you, Gil, for  
13       catching the error here. 49651 actually did  
14       have 4,620 procedures reported. That's an  
15       error. But everything else on the slide was  
16       correct.

17              The black bolded procedure codes are  
18       those that are already in 5342. The purple are  
19       the ones that we're proposing. Even if you move  
20       them, there are still 80 procedure codes with  
21       over 100,000 single-frequency procedures in  
22       5361.



1                   And it would mean that there would be  
2                   15 CPT codes with about 76,000 single frequency  
3                   procedures in 5342. That's my presentation  
4                   today. Thank you.

5                   DR. HAMBRICK: Thank you. For the  
6                   panel, APC 5361 is on Pages 111 through 113.  
7                   And APC 5342 is on Page 111. Are there any  
8                   questions for Ms. Guthery from the panel?

9                   DR. DAWSON: Yes. I have a question.  
10                  The fact that the open, two open procedures,  
11                  open appendectomy and open inguinal hernia were  
12                  placed in the higher level APC, isn't that an  
13                  indication that there was, there's more resource  
14                  utilization when it's in, it turns into an open  
15                  procedure, is my understanding.

16                  MS. GUTHERY: I, we didn't even  
17                  approach it from those procedures that convert  
18                  from a laparoscopic or a robotic-assisted.

19                  DR. DAWSON: Okay. But leave  
20                  conversion behind. Just the open procedures.  
21                  The open procedures are more resource  
22                  utilization. Am I wrong about that?

1 MS. GUTHERY: Actually, for soft tissue  
2 surgery, the open procedures are typically less.  
3 I think if we go back and look, I think, I can't  
4 remember if it's open initial inguinal hernia or  
5 open appendectomy, they're very similar to the  
6 laparoscopic approach which --

7 But actually, the geometric mean costs  
8 for the lap approach are more aligned to what we  
9 see the payment rate assigned for, or proposed  
10 for '26 to be, to belong in APC 5342. So open  
11 appendectomy is at \$7,108. Lap appendectomy is  
12 at 60, it's, they're about \$400 apart.

13 The other two, the initial and blocked  
14 inguinal hernia repair that are open, the  
15 geometric mean costs are actually much lower  
16 than their laparoscopic counterparts. Yet  
17 they're still assigned the APC 5342. Does that  
18 answer your question?

19 DR. HAMBRICK: Any other questions?

20 MS. DAVIS: Yes. That does answer my  
21 question. So it's a little confusing to me as  
22 to why those two were assigned to the higher APC

1 to begin with.

2 MS. GUTHERY: I think it was a  
3 situation where CMS had always separated based  
4 on the approach. And with the advent of the new  
5 codes and the way they were described by AMA,  
6 it, like I said, left them in a conundrum.

7 Like, how are we supposed to do this  
8 now? And now it's coming down to cost and  
9 clinical similarity, which is why we're asking  
10 for the change.

11 DR. HAMBRICK: Any other questions from  
12 panelists? Anyone in queue, Ms. Davis? Anybody  
13 in the chat?

14 MS. CESNIK: There's no raised hands.

15 DR. HAMBRICK: Thank you.

16 MS. CESNIK: There's no one in the  
17 chat.

18 DR. HAMBRICK: Thank you. Are there  
19 any recommendations with respect to this  
20 presentation from the panel?

21 MR. FAZIO: Yes. I recommend moving  
22 CPTs 49650, 49651, and 44970 to APC 5342, to be

1 consistent with the costs of the case with  
2 comparable CPTs.

3 DR. HAMBRICK: Thank you. Is there a  
4 second?

5 DR. BEAN: Second.

6 DR. HAMBRICK: Thank you.

7 PARTICIPANT: Question.

8 DR. HAMBRICK: Discussion on the  
9 motion? Sorry? Okay. Discussion on the  
10 motion? All those in favor signify by saying  
11 aye.

12 (Chorus of aye.)

13 DR. HAMBRICK: Opposed, nay. Any  
14 abstentions? Thank you very much.

15 MS. GUTHERY: Thank you.

16 DR. HAMBRICK: Now we'll have a  
17 presentation on APC assignment for  
18 Cardiorespiratory Assessment. Ms. Nicole Marcos  
19 will give the CMS overview, followed by a  
20 presentation by Steve Lee from MediPines.

21 MS. MARCOS: Thanks, Dr. Hambrick. Hi.  
22 Hi. I'm Nicole Marcos from the Division of

1 Outpatient Care. And I will provide the CMS  
2 overview on MediPines' presentation on AGM 100.

3 The AGM 100 service is described by CPT  
4 Code 0893T, which became effective on July 1st  
5 of 2024. AGM 100 is the non-invasive assessment  
6 of blood oxygenation, gas exchange efficiency,  
7 and cardiorespiratory status with physician  
8 interpretation report.

9 The service is performed by placing an  
10 integrated pulse oximeter on the patient's  
11 finger, a nose clip on the patient's nose, and  
12 having the patient breathe through a mouthpiece  
13 to collect samples of ambient air, along with  
14 the patient's breath.

15 The test could be performed by a  
16 trained healthcare professional. And the  
17 results are reviewed by a physician.

18 For CY 2026, CMS proposed to continue  
19 to assign CPT Code 0893T to APC 5733, which is  
20 for Level 3 minor procedures, and includes other  
21 oxygen measurement tests.

22 APC 5733 has a proposed payment rate of

1       approximately \$60. We currently do not have any  
2       claims data for CPT Code 0893T.

3               In a moment, you will hear a  
4       presentation regarding an APC reassignment  
5       request for CPT Code 0893T. This concludes my  
6       presentation. And thank you very much.

7               DR. HAMBRICK: Thank you. For the  
8       panel there's APC 5733, which can be found on  
9       Page 185. And 5722 on Page 178. You may go  
10      ahead, Steve Lee.

11              MR. LEE: Good morning. Thank you,  
12      everyone on the panel. We are requesting, if  
13      you can flip to the first slide. We are  
14      requesting reassignment of CPT 0893T to APC 5723  
15      from APC 5733.

16              The current assignment is misaligned  
17      with both the resource utilization and clinical  
18      methodology, creating unnecessary barriers to  
19      beneficiary access.

20              And why is reassignment to APC 5723  
21      necessary on a clinical basis grounds? CPT  
22      0893T uses the identical clinical methodology of

1 another existing CPT Code. 94681, which CMS has  
2 already applied to APC 5723, starting in 2026.

3 This is the appropriate classification.  
4 So, we submit an addendum to reference this  
5 update in the master deck. So, the document  
6 that is 5722, which was '25, but effective '26  
7 it will be updated to 5723.

8 So, just to be clear, our ask is  
9 reassignment to APC 5723. Both CPT 0893T and  
10 94681 involve acts of gas analysis with oxygen  
11 and carbon dioxide measurements for evaluating  
12 cardiorespiratory functions. And both require  
13 physician interpretation.

14 Please flip to the next slide, the  
15 next. The AMA's official definition for 0893T,  
16 the non-invasive assessment of the patient's  
17 blood oxygenation, PO2, gas exchange efficiency,  
18 non-invasive Aa gradient, and cardiorespiratory  
19 status with physician interpretation in report.

20 While 94681 primarily used to evaluate  
21 chronic conditions, such as COPD progression and  
22 exercise capacity, 0893T represents an

1 advancement designed for acute patient care in  
2 the emergency setting.

3 It directly addresses impairment  
4 severity, requires less patient effort, and  
5 provides critical physiological insights as the  
6 patient's heart and lung function are  
7 deteriorating.

8 To do this, you evaluate gas exchange  
9 impairment with high precision and clinical  
10 fidelity in serious conditions, such as  
11 pulmonary embolism, respiratory failure, and  
12 heart failure.

13 These life-threatening scenarios with  
14 overlapping symptoms, breathing difficulty, and  
15 chest pain, demand complex physiological  
16 evaluation using precision equipment at the  
17 point of care by physician-level interpretation  
18 that cuts through diagnostic uncertainty.

19 Particularly useful in the emergency  
20 setting. So, it belongs in APC 5723 based on  
21 comparable clinical grouping.

22 Second, 0893 does not belong in APC



1 5733. That group includes minor procedures like  
2 nail trimming and earwax removal, requiring no  
3 special tools.

4 In contrast, APC 5723 includes cardiac  
5 and respiratory assessment using specialized  
6 equipment such as cardiopulmonary function  
7 testings, CPET, PFT spirometric, all of which  
8 require professional interpretation.

9 0893T clearly aligns with this group.  
10 It is for cardiorespiratory assessment,  
11 precision, uses precision equipment, and  
12 requires physician-level interpretation.

13 And finally, the resource cost impact  
14 is significant. This misclassification creates  
15 unsustainable losses for healthcare providers.  
16 It costs providers \$360 for an assessment, while  
17 the current payment is only \$59. Resulting in a  
18 \$300 loss.

19 This gap makes it financially not  
20 feasible for providers to offer this service,  
21 thereby limiting access for beneficiaries.

22 MS. ARTIGUE: Pardon me. This is your

1 one-minute warning.

2 MR. LEE: Thank you. So, we  
3 respectfully request reassignment of CPT 0893T  
4 to APC 5723, where it truly belongs, based on  
5 resources, clinical purpose, and diagnostic  
6 methodology comparability.

7 This change will eliminate provider  
8 barriers and help ensure Medicare beneficiaries  
9 have access to this life-saving diagnostic  
10 capability in the hands of front line physicians  
11 and medical staff. Thank you for your  
12 consideration.

13 DR. HAMBRICK: Thank you. Dr. Manaker.

14 DR. MANAKER: Thanks for the  
15 presentation. I've got a couple of clinical  
16 questions for you. First of all, the patient's  
17 got to wear a nose clip and then breathe through  
18 the device, correct?

19 MR. LEE: That's right.

20 DR. MANAKER: So, how do you do this in  
21 somebody who's hypoxic and needs nasal cannula  
22 oxygen?

1           MR. LEE: So, when they are present, it  
2 is easy. A lot of the patients would have, it's  
3 half and half. The patients who actually need  
4 to be intubated right away, this would not be  
5 used for.

6           When they're presenting with low  
7 saturation on the low side, and vital signs have  
8 some abnormal numbers, but it's not clear, it  
9 brings clarity for the patient.

10          And generally, in a typical clinic,  
11 there's almost 97 percent compliance from a  
12 patient being able to breathe through the  
13 mouthpiece.

14          DR. MANAKER: And can they do this  
15 lying down on a gurney or an exam table in ED,  
16 or an urgent care center, for example?

17          MR. LEE: Mm-hmm.

18          DR. MANAKER: Okay. And what exactly  
19 does the device print out? Your last slide sort  
20 of showed a number of values there. But there's  
21 a differential diagnosis, right?

22          It doesn't tell you if the patient is

1 in heart failure, having a pulmonary embolism,  
2 or having pneumonia. It just says your, an  
3 algorithm describing gas exchange.

4 MR. LEE: Yes. The gas exchange, half  
5 of the measurements are direct sampling, you  
6 know. And then the other half of the  
7 measurements that you see on the screen are  
8 calculated.

9 And clinicians are using these to  
10 assess. The pulmonary embolism is a classic  
11 case where in an ER they saw the elevated oxygen  
12 deficit, which is Aa gradient, the elevated  
13 oxygen deficit. End-tidal CO2 was low, PO2 was  
14 substantially lower than expected, and they  
15 suspected pulmonary embolism.

16 And they still need to take the  
17 complementary test of a CTPA. But it helps them  
18 diagnose and triage much more rapidly in their  
19 disposition decision.

20 And also, carbon dioxide retention is a  
21 serious issue. So if you have a carbon dioxide  
22 issue, what is the ADA gradient, or the elevated

1 oxygen deficit is that they're looking at? And  
2 then they help narrow down their diagnosis.

3 DR. MANAKER: Well, is it, yes. But  
4 there's a huge differential diagnosis. And  
5 they're still going to send off a D-dimer. If  
6 there's a high enough suspicion, you get a chest  
7 CT angiogram anyhow.

8 I mean, I, and patients who are short  
9 of breath, I just don't see them wearing a nose  
10 clip and breathing through the device for one or  
11 two minutes when they're short of breath, and  
12 typically going to need to get some supplemental  
13 oxygen.

14 MR. LEE: Yes. So, typically, the  
15 average respiratory patient coming in, the  
16 average is about 97 seconds to get steady state.  
17 So the state, so you have no more like that.

18 It's not really two minutes. But it  
19 does range depending on the condition. And most  
20 people tolerate quite well, based on our  
21 experience.

22 DR. MANAKER: Okay. All right. Thank

1       you.

2               MS. ARTIGUE: This is Jennifer Artigue.  
3       I have a question. Ms. Marcos, did you report  
4       that there were no claims data for Code 0893T?  
5       Did I understand that correctly?

6               MR. LEE: We believe that there --

7               MS. MARCOS: Yes.

8               MR. LEE: -- based on the provider.  
9       Some of that was we believe that the  
10       availability became this year. So by the end of  
11       the year, we anticipate several hundred to be  
12       brought in.

13              MS. ARTIGUE: Okay. I was just curious  
14       if the code was effective July of '24, you know,  
15       why we didn't have any claims data to be able to  
16       evaluate the actual costs.

17              MS. MARCOS: Yes. Looking at the two  
18       times data no claims yet for it. But because  
19       it's towards the end of the year, it could make  
20       sense.

21              MS. ARTIGUE: Okay. Thank you.

22              DR. DAWSON: So, I also have a

1 question. This is Nancy Dawson. Just to  
2 clarify, you're requesting that 0893T go into  
3 APC 5722, not 5723? I thought I heard you say  
4 5723.

5 MR. LEE: Yes. So we are requesting  
6 APC 5723 effective calendar 2026, because as of  
7 2025 it was under APC 5722. But it's moving to  
8 APC 5723.

9 We're asking it to be in the same APC  
10 classification that existing PFC tests that are  
11 doing carbon dioxide and oxygen assessment of  
12 existing CPT Code 94681, where it is slated to  
13 into APC 5723. So just to be clear, our request  
14 is APC 5723.

15 MS. ARTIGUE: 5723. Okay. And just to  
16 reiterate Dr. Manaker's question. The patient  
17 sits and has this monitor put on them, correct?

18 MR. LEE: Patient is just naturally  
19 breathing.

20 MS. ARTIGUE: Naturally breathing. So  
21 in that way, it's really not like a PST, because  
22 they're not doing active, there's no active

1 measurement of lung volume, or anything like  
2 that from what the patient's doing. It's really  
3 more like the patient sitting there and they  
4 have a monitor on that's calculating.

5 MR. LEE: That's right.

6 MS. ARTIGUE: Okay.

7 DR. HAMBRICK: Dr. Tettelbach.

8 DR. TETTELBAACH: Yes. I have a couple  
9 of questions. So one thing I wanted to point  
10 out that it would be like, it mentioned here  
11 that carbon monoxide, it could detect that.

12 But yet most EMTs and EDs, you know,  
13 have already carbon monoxide type detectors.  
14 And actually when you do correlations with  
15 these, with direct blood gas, you know, like an  
16 ABI, you know, an ABG, they can be off quite a  
17 bit.

18 So, I'm not quite sure what the  
19 verification, or how often this device has to be  
20 recalibrated.

21 Also, does it give, you know, to  
22 understand folks who are metabolically off, I



1 mean, does it give a calculation of a, you know,  
2 if the patient's acidotic or alkalotic of this?

3 Because generally these are numbers you  
4 need to, for a deeper dive of diagnoses. If  
5 you're looking at others, what respiratory  
6 issues are? It may not just be, you know, it  
7 could be an acidotic, you know, alkalotic  
8 mismatch.

9 But also, if there's a shunting, or  
10 whatnot. But yes. I'm just, I'm curious if,  
11 you know, knowing that, and really there's no  
12 claims data because there's other tools, what's  
13 the, you know, where do you think the adoption  
14 will come from?

15 Will this change create a better  
16 environment for adoption? Those are my  
17 questions.

18 MR. LEE: Yes. If I could answer some  
19 aspects of the pathology. So we have a non-  
20 invasive PO2, which is equivalent to the  
21 arterial blood gas PO2 test that you will get,  
22 the gold standard.

1                   And the study of Duke and UCSD  
2       researchers have conducted a study where they  
3       took a normal subject and then exposed to a --  
4       to hypoxic induced state.

5                   The non-invasive PO2 comes out of this  
6       device to the invasive PO2 that you get from  
7       arterial blood gas has a correlation of .97,  
8       bias of 0.7, effectively, once one relationship  
9       was established. So non-invasive PO2 is as good  
10      as the invasive PO2 in a full range of human  
11      physiology.

12                  So, the next study that was also  
13      published by the UCSD researchers, these all  
14      came out just very recently, where they took,  
15      they even, you know, it was a prospective study  
16      in two academic centers, where a patient was  
17      reaching the respiratory failure requiring  
18      intervention.

19                  In this case, it was supplemental  
20      oxygen. The AUC area of the curve was .98. And  
21      it is believed to be one of the highest  
22      measurements that we know of as a respiratory

1 failing patients of all mixed types, from COPD,  
2 pulmonary embolism, and what have you.

3 And so what it really offers, this so-  
4 called non-invasive Aa gradient of arterial  
5 minus arterial, ability for gas to go from the  
6 lung to the blood site. We just do it non-  
7 invasively.

8 And because it's, technology's  
9 relatively new, people are not quite familiar  
10 with all the potential benefits of this. So we  
11 believe that a change over time.

12 And as far as emergency patients who  
13 are coming in, and why pulse ox and others are  
14 useful tools, but still limiting with vital  
15 signs, is that 60 percent of patients who come  
16 into ED have that normal carbon dioxide level.

17 And that normal carbon dioxide directly  
18 impacts the PH. The blood abnormality still has  
19 to directly impact the PH value. Therefore,  
20 whatever you're seeing may not be seeing the  
21 true saturation, which doesn't equate to PO<sub>2</sub>,  
22 because of the dissociation curve being shifted

1 back and forth.

2 So, this tool can provide an  
3 alternative, sort of a, is useful for diagnostic  
4 workups in an ED, physicians. And they have  
5 used this to identify who needs supplemental  
6 oxygen, and how do you escalate care if you  
7 change the body position.

8 The essential people have done it quite  
9 well, where during the pandemic, they were able  
10 to assess that the perfusion and ventilation  
11 mismatch was minimized.

12 So they can do different maneuvering on  
13 the patient to improve gas exchange on the  
14 patient, as well as differential diagnosis. For  
15 example, in a pulmonary embolism case, they were  
16 able to identify.

17 Because a lot of times, you know, they  
18 do a D-dimer. And D-dimer will say positive.  
19 And you go to CPT, and it comes back negative,  
20 because D-dimer has a high sensitivity but low  
21 specificity.

22 So they were able to use the tool to

1 fast triage and direct patients appropriately.

2 DR. HAMBRICK: Okay. Thank you for  
3 your response. And if we can sort of talk about  
4 the clinical coherence and the resource costs  
5 for the OPPS. Are there any more questions from  
6 panelists? Are there any in queue, Ms. Davis?  
7 Any hands raised?

8 MS. DAVIS: Currently, there are no  
9 raised hands.

10 MS. CESNIK: No questions --

11 DR. HAMBRICK: Any questions in the  
12 chat?

13 MS. CESNIK: -- in the chat. No. No  
14 questions.

15 DR. HAMBRICK: Thank you. Is there a  
16 recommendation from the panel with respect to  
17 this presentation? Okay. Hearing none, thank  
18 you very much, Steve Lee.

19 We are going to press ahead to the  
20 afternoon. And the first one we're going to do  
21 is NeuroPace, Allie D'Accurzio and Joel Becker.  
22 And Tonya Gierke will give the doc, the CMS

1 overview.

2           It's a few slides ahead. I didn't want  
3 to break up Erik's presentation. So, if you can  
4 skip a few slides ahead to the second  
5 presentation of the afternoon for NeuroPace.  
6 There we go. Thank you. Skull-Mounted  
7 Neurostimulator Procedure. Thank you.

8           MS. GIERKE: Hi, everyone. My name is  
9 Tonya Gierke again. And I am with the Division  
10 of Outpatient Care. And I will cover the CMS  
11 overview and background information for  
12 NeuroPace's presentation.

13           CPT Code 61891 became effective January  
14 1st, 2024. The descriptor for CPT Code 61891 is  
15 revision or replacement of skull skull-mounted  
16 cranial neurostimulator pulse generator or  
17 receiver with connection to depth and/or  
18 cortical strip electrode arrays.

19           In the Calendar Year 2026 ASC/OPPS  
20 proposed rule, we've proposed to continue to  
21 assign CPT Code 61891 to APC 5464, Level 4  
22 stimulator and related procedures, with a

1 proposed payment rate of \$20,126.69, based on  
2 clinical similarities between CPT Code 61891 and  
3 other cranial nerve stimulator codes currently  
4 assigned to APC 5464.

5 NeuroPace's request is to reassign CPT  
6 Code 61891 from proposed APC 5464 to APC 5465,  
7 Level 5 neurostimulator and related procedures  
8 for Calendar Year 2026.

9 Because they state that assignment to  
10 APC 5465 represents a better alignment of  
11 hospital costs and payment for replacement  
12 procedures for the skull-mounted cranial  
13 neurostimulators. And this concludes my  
14 presentation. Thank you.

15 DR. HAMBRICK: Thank you. You may go  
16 ahead, NeuroPace.

17 MS. D'ACCURZIO: Great. Thank you.  
18 I'm Allie D'Accurzio, the Director of  
19 reimbursement at NeuroPace. And I want to thank  
20 you for the opportunity to present our request  
21 for an APC reassignment for CPT Code 61891.

22 Next slide, please. Just a brief

1 overview of the RNS system, which is the only  
2 FDA-approved skull-mounted cranial  
3 neurostimulator. It's for the treatment of  
4 drug-resistant focal epilepsy.

5 The implantable components are the  
6 neurostimulator, which is implanted in the skull  
7 via craniectomy. And then two electrode arrays  
8 that can be implanted either on the surface of  
9 the brain, which is the strip electrode, or in  
10 the brain, which is a depth electrode.

11 The electrodes are connected to the  
12 neurostimulator. And once implanted, it can be  
13 programmed to detect certain electrical  
14 patterns. And it releases stimulation in  
15 response to those detections.

16 The neurostimulator is constantly  
17 collecting electrographic data and storing it so  
18 that the physician can review it to inform  
19 treatment.

20 Next slide, please. When the  
21 neurostimulator battery is at the end of  
22 service, it needs to be replaced. This is



1 predominantly done in the hospital outpatient  
2 setting due to the nature of the procedure.

3 It is described, replacements are  
4 described with CPT Code 61891. It is a new code  
5 effective January 2024 as part of an effort to  
6 differentiate between skull-mounted stimulators  
7 and cranial neurostimulators implanted in a  
8 subcutaneous pocket in the chest, reported with  
9 CPT Codes 61885 and 61886.

10 Prior to 2024, the replacement of a  
11 skull-mounted cranial neurostimulator was  
12 reported with 61886 and mapped to APC 4565.  
13 However, CMS assigned 61891 to APC 5464 as the  
14 code includes a replacement or a revision.

15 As a result, hospitals are being  
16 significantly underpaid for the replacement  
17 procedure under APC 5464. We believe this is an  
18 unintended consequence of the CPT process, which  
19 focuses on physician work, and not hospital  
20 payment.

21 Next slide, please. The reason we feel  
22 it's an unintended consequence is that revision

1 procedures are extremely rare, given that the  
2 neurostimulator is implanted in the skull.

3 Our company tracks every procedure  
4 related to the device since FDA approval in  
5 2013. And there have only been 12 revision  
6 procedures that have occurred in that timeframe.  
7 And most of these are due to infection in the  
8 tray in which the neurostimulator sits and has  
9 to be replaced.

10 There have been no neurostimulator  
11 revision procedures performed in 2024,  
12 indicating that all of the Medicare claims  
13 associated with CPT Code 61891 are replacement  
14 procedures.

15 Next slide, please. So our request is  
16 that CMS reassign 61891 to APC 5465 for Calendar  
17 Year 2026. A review of the claims data that was  
18 published with the proposed rule supports this.

19 The geometric mean cost for 61891 is  
20 \$32,487, which is significantly higher than the  
21 cost of other procedures in 5464, and is better  
22 aligned with the costs of other procedures in

1 5465, as demonstrated in the tables below on the  
2 slide.

3 In addition, CMS is proposing to  
4 reassign 61885, which is a cranial  
5 neurostimulator implanted in the subcutaneous  
6 pocket on the chest from APC 5465, I'm sorry,  
7 from 5464 to APC 5465 for Calendar Year 2026,  
8 which has a comparable geometric mean cost of  
9 \$61,891.

10 MS. ARTIGUE: Pardon me. One minute  
11 reminder.

12 MS. D'ACCURZIO: Thank you. As  
13 previously mentioned, all nine claims represent  
14 replacement procedures. No revisions were  
15 performed in 2024.

16 Next slide, please. In addition to  
17 better alignment of costs, 5465 represents a  
18 more appropriate payment level for 61891. As  
19 mentioned, hospitals are currently being  
20 underpaid under 5464, with a difference of  
21 approximately \$12,000 between cost and payment.

22 So, reassignment to 5465 would

1 significantly narrow that gap. And again, this  
2 is a similar scenario in terms of cost and  
3 payment with CPT Code 61885, and moving from APC  
4 5464 to 5465.

5 Next slide, please. And just in  
6 summary, we are requesting that the panel  
7 recommend that CMS reassign CPT Code 61891 from  
8 5464 to 5465 for Calendar Year 2026, as we  
9 believe this represents a better assignment of  
10 hospital costs and payment for a replacement  
11 procedure for skull-mounted cranial  
12 neurostimulators. Thank you.

13 DR. HAMBRICK: Thank you. Are there  
14 any questions for Ms. -- I was doing pretty good  
15 before, D'Accurzio. But I --

16 MS. D'ACCURZIO: Yes. D'Accurzio.

17 (Simultaneous speaking.)

18 MS. D'ACCURZIO: That's good.

19 DR. HAMBRICK: Yes. Any questions from  
20 the panel? Is there anybody in queue, Ms.  
21 Davis? Any hands raised?

22 MS. DAVIS: Currently, there are no

1 raised hands.

2 DR. HAMBRICK: Thank you. Anybody in  
3 the chat?

4 MS. CESNIK: No questions in the chat.

5 DR. HAMBRICK: All right. Does any  
6 panel member wish to make a recommendation with  
7 respect to this presentation?

8 DR. MANAKER: Yes. I'd point out that  
9 there are several revisions and replacements in  
10 APC 5465. So, I move for reassignment of CPT  
11 Code 61891 from APC 5464 to APC 5465. Ms.  
12 D'Accurzio, you convinced me.

13 MS. ARTIGUE: I second.

14 DR. SETH: I will third that as well.  
15 Great job.

16 DR. HAMBRICK: Any discussion? All  
17 those in favor indicate by saying aye.

18 (Chorus of aye.)

19 DR. HAMBRICK: Opposed, nay. Any  
20 abstentions?

21 Okay. Well, I think we can stop here  
22 for lunch, since you all did such a good job.

1       It's 12:00. We'll see you, and we have 50  
2       minutes for lunch. I'll see you back at 12:50  
3       p.m., 12:50 p.m.

4               MS. D'ACCURZIO: Thank you.

5               DR. HAMBRICK: Thank you.

6               (Whereupon, the above-entitled matter  
7       went off the record at 12:01 p.m. and resumed at  
8       12:50 p.m.)

9               DR. HAMBRICK: Good afternoon,  
10       everybody. It's 12:50 p.m. here on the East  
11       Coast. We're going to start with the  
12       presentation of Neurostimulator and Related  
13       Services.

14               Erick Chuang will give us the overview  
15       from CMS. Then we'll have a presentation from  
16       Gary Delhougne from LivaNova, Brian Carlson from  
17       MicroTransponder, and Seamus Jackson from ZOLL.

18               You can go ahead, Mr. Chuang.

19               MR. CHUANG: Thanks, Dr. Hambrick.

20               Hello, everyone. My name is Erick Chuang,  
21       and I'm an analyst in the Division of Outpatient  
22       Care. I'll be providing an overview of the

1 Neurostimulator and Related Procedures APC  
2 Series. In the calendar year 2015 OVPS ASC Final  
3 Rule, we finalized the restructuring of  
4 Neurostimulator procedure-related APCs into a  
5 four-level series.

6 In reviewing the claims data available  
7 for the calendar year 2021 OVPS proposal, we  
8 believe that it was appropriate to create an  
9 additional Neurostimulator and Related  
10 Procedures level between what were then the  
11 level 2 and 3 APCs.

12 Creating that APC allowed for a  
13 smoother distribution of the cost between the  
14 different levels based on their resource costs  
15 and clinical characteristics. Therefore, we  
16 finalized a five-level APC structure for the  
17 Neurostimulator and Related Procedures Series in  
18 the calendar year 2021 OVPS.

19 In the calendar year 2023 OVPS proposed  
20 rule, we proposed to maintain the five-level APC  
21 structure for the Neurostimulator and Related  
22 Procedures Series.

1                   However, recognizing commenters'  
2 concerns regarding the granularity of the  
3 current APC levels and their request to create  
4 an additional level to address those concerns,  
5 we solicited comments on the creation of a new  
6 level 6 APC in the series. While some public  
7 comments supported the creation of a level 6  
8 APC, others supported maintaining the five-level  
9 structure.

10                   We also received comments requesting  
11 that code 0424T, insertion or replacement of  
12 Neurostimulator system for treatment of central  
13 sleep apnea, complete system, transgenus  
14 (phonetic) placement of right or left  
15 stimulation lead, sensing lead implantable pulse  
16 generator, be temporarily assigned to New Tech  
17 APC 1581, which had a calendar year 2023 OPPS  
18 payment rate of \$50,000.50.

19                   In the calendar year 2023 OPPS final  
20 rule, based on public comments, we maintained  
21 that five-level structure for the APC series and  
22 finalized the temporary assignment of CPT code



1       0424T to New Tech APC 1581. We noted that we  
2       could continue to monitor the claims and cost  
3       data as they are available.

4               In the calendar year 2024 OPPS, we  
5       maintained the five-level structure for the  
6       Neurostimulator and related procedures APC. We  
7       assigned CPT code 64568, open implantation of  
8       cranial nerve, e.g., vagus nerve,  
9       Neurostimulator electrode array and pulse  
10      generator, APC 5465, level-five Neurostimulator  
11      and related procedures.

12              We assigned CPT code 0266T,  
13      implantation or replacement of carotid sinus  
14      barrel flex activation device, total system,  
15      includes generator placement, unilateral or  
16      bilateral lead placement, intraoperative  
17      interrogation, programming, and repositioning  
18      when performed.

19              And 33276, insertion of phrenic nerve  
20      stimulator system, pulse generator and  
21      stimulating lead, including vessel  
22      catheterization, all imaging guidance and pulse

1 generator, initial analysis with diagnostic mode  
2 activation when performed to APC 1580 new  
3 technology level 43 with a range from \$40,001 to  
4 \$50,000.

5 In the calendar year 2026 OPPS, we  
6 propose to maintain the five-level APC structure  
7 and continue to request comment on the creation  
8 of an additional level six APC in the series.

9 In the following presentation, interested  
10 parties will discuss various requests related to  
11 the Neurostimulator APC series and its assigned  
12 codes.

13 These include the request to create a  
14 level six APC, as well as the request to assign  
15 CPT code 64568 to Neurostimulator APC 1580.

16 And this concludes my presentation.

17 DR. HAMBRICK: Thank you.

18 Are there any questions for Mr.  
19 Chuang?

20 If not, Gary Delhougne, why don't you  
21 go ahead for LivaNova.

22 MR. DELHOUGNE: Great. Thank you so

1 much. Once again, my name is Gary Delhougne,  
2 and I represent LivaNova, the maker of a vagus  
3 nerve stimulation system primarily focused on  
4 the treatment of patients with drug-resistant  
5 epilepsy.

6 Next slide, please. So this group of  
7 companies comes back to the panel this year  
8 requesting that it reiterate its support for the  
9 creation of a level six Neurostimulator APC, or  
10 that it treats 64568 consistently, and move it  
11 into new technology APC 1580 for calendar year  
12 2026, for three reasons.

13 First, hospital losses for 64568 are a  
14 statistical outlier. Second point, the  
15 distribution of costs in the level five APC are  
16 meaningful and should not be viewed as  
17 appropriate.

18 Third point is going to be retaining  
19 other codes in new technology APC 1580, but not  
20 moving 64568 is an inconsistent practice of  
21 managing APCs. Next slide, please.

22 64568 is a loss outlier for hospitals

1 requiring action by CMS. LivaNova admits that  
2 for the majority of procedures, the argument  
3 that some procedures are overpaid, some are  
4 underpaid, works out.

5 The graph on the right shows the  
6 majority of procedures hug that zero or break-  
7 even point. But when you start moving out to  
8 the tails of a profit and loss distribution, we  
9 believe CMS should take action.

10 Specifically, 64568 falls near the  
11 extreme lower tail of a profit and loss review  
12 or around the 0.65 percentile, meaning 64568 is  
13 a greater loss to hospitals than 99.35% of all  
14 other J1 procedures in the OPPS. And we believe  
15 that at this level of movement down the tail,  
16 CMS should take action. Next slide.

17 The GMC distribution for the level 5  
18 grouping is meaningful and should not be viewed  
19 as appropriate. In the proposed rule, CMS  
20 stated the neurostimulator family provides for  
21 an appropriate distribution of cost and clinical  
22 similarity across APCs.

1           Within the level 5 grouping, there are  
2           a majority of procedures that huddle around  
3           32,000 to 35,000, and another grouping of our  
4           level 6 design codes for 42,000 to 47,000.  
5           We believe that delta is meaningful.

6           Furthermore, in the proposed rule, as CMS  
7           was looking at creating a level 7  
8           musculoskeletal APC, they stated that there was  
9           a bimodal distribution of geometric means in  
10          that musculoskeletal level 6, with a clustering  
11          around 17,000 to 18,000 and 27,000 to 28,000.

12          CMS stated that this is a meaningful  
13          distinction between service costs supporting the  
14          creation of a new or additional APC level. So, I  
15          ask this panel, why is one APC grouping's  
16          \$11,000 difference meaningful, and another APC's  
17          grouping of \$11,000 or more is appropriate?  
18          Next slide.

19                 In the absence of CMS creating a level  
20          6 APC, we believe CMS is treating 64568  
21          disparately by not including it in the new  
22          technology APC 1580. As Erick just mentioned,

1 in prior rulemaking, 2023 and 2024, CMS put  
2 33276 into New Tech APCs 1581, then 1580.

3 In 2024 rulemaking, CMS followed that  
4 rationale by putting 0266T into APC 1580,  
5 stating that its GMC at the time of \$47,300 was  
6 substantially higher --

7 MR. BAILEY: Pardon me. One minute  
8 remaining.

9 MR. DELHOUGNE: Thank you --  
10 substantially higher than the payment rate for  
11 APC 5465. So we believe those were the  
12 appropriate decisions made back then, but to  
13 continue those codes in APC 1580 for their  
14 fourth and third years, but not 64568, is  
15 treating us differently when there are enough  
16 single-frequency claims or similar single-  
17 frequency claims to 64568. Next slide.

18 Once again, we reiterate and ask the  
19 panel to continue its support of a level 6  
20 neurostimulator APC for this group of codes, or  
21 that it treat 64568 consistently and move it to  
22 APC 1580, either for calendar year 2026, for the

1 three points that I just made. Thank you.

2 DR. HAMBRICK: Thank you. Are there  
3 any questions? The way we'll handle this  
4 grouping is if we have questions on individual  
5 presentations alone, then we'll ask them right  
6 after the presentation, but we'll reserve the  
7 discussion for the whole concept until the end  
8 of the third presentation.

9 Are there any questions for Mr.  
10 Delhougne? Okay. Then let's move on to Brian  
11 Carlson from Microtransponder, Inc.

12 MR. CARLSON: Next slide, please. Good  
13 afternoon. My name is Brian Carlson. I'm the  
14 Vice President of Reimbursement and Market  
15 Access with Microtransponder, and thank you to  
16 the panel for having me today.

17 We are requesting reassignment of CPT  
18 code 64568 to New Tech APC 1580, effective  
19 January 1, 2026. This change is needed to  
20 preserve Medicare beneficiary access to Vivistim  
21 after transitional pass-through expires.  
22 Next slide, please.

1 Vivistim is the only FDA-approved  
2 neurostimulation device for chronic ischemic  
3 stroke patients with moderate to severe arm  
4 impairment. The key to this therapy is that it  
5 pairs vagus nerve stimulation with  
6 rehabilitation therapy to help restore motor  
7 pathways.

8 This results in meaningful and  
9 sustained gains in arm and hand function. Next  
10 slide, please. Medicare patients are  
11 experiencing real improvements with Vivistim,  
12 and this is a real patient that we're showing  
13 here.

14 And, for example, as shown in the  
15 pictures here, a patient named Kathy was able to  
16 regain the ability to write after eight weeks of  
17 therapy, which was not possible originally after  
18 her stroke. This outcome is a good example of  
19 the unique benefit of this therapy to Medicare  
20 patients. Next slide, please.

21 Vivistim was FDA-approved in 2021 and  
22 received a breakthrough device designation. CMS



1 granted a new technology add-on payment and  
2 transitional pass-through status, both of which  
3 expire in 2025.

4 This therapy is predominantly implanted  
5 in a hospital outpatient setting, and without  
6 APC reassignment in 2026, hospitals will face a  
7 significant payment shortfall that threatens  
8 Medicare patient access. Next slide, please.

9 Medicare hospital claims analysis shows  
10 that the total procedure costs to implant the  
11 Vivistim system are greater than \$50,000. CPT  
12 code 64568 is assigned to APC 5465, which will  
13 pay around \$31,000 in 2026, as proposed.

14 Without APC reassignment, hospitals  
15 face an almost \$19,000 or approximate \$19,000  
16 shortfall per case starting in January. This  
17 financial gap will limit Medicare patients'  
18 access to the therapy. Next slide, please.

19 APC 5465 is dominated by high-volume,  
20 lower-cost procedures that cluster around  
21 \$32,000 with regard to cost. Vivistim, with  
22 reported costs of over \$50,000 and 74 claims, is

1 a low-volume, high-cost procedure that gets  
2 drowned out.

3 The other therapy that uses CPT 64568,  
4 as Gary mentioned previously in the earlier  
5 presentation, has total claims combined that  
6 show 289 claims with total costs of \$47,613.

7 In 2026, another lower-cost procedure  
8 will be added to 5465, pushing the average down  
9 further. This leaves hospitals with about a  
10 \$19,000 loss per Medicare case, which we believe  
11 is unsustainable and will reduce patient access.  
12 Next slide, please.

13 CMS has reassigned similar low-volume,  
14 high-cost stimulation technologies, such as  
15 carotid baroreflex and phrenic nerve  
16 stimulation, to new technology APCs after TPT  
17 expired. Vivistim costs are consistent with  
18 these procedures, and we believe should be  
19 treated the same way to preserve access. Next  
20 slide, please.

21 We respectfully ask this panel to  
22 recommend assigning CPT code 64568 to New Tech

1 APC 1580. This is consistent with CMS  
2 precedent. It reflects actual costs of the  
3 procedure, and most importantly, it prevents  
4 loss of access for Medicare stroke survivors.

5 Next slide. Thank you for your time.  
6 We believe this change is essential to protect  
7 access for patients who can regain independence  
8 through Vivistim rehabilitation therapy. If you  
9 have any questions, I welcome them.

10 DR. HAMBRICK: Any questions for Mr.  
11 Carlson?

12 MR. FAZIO: I just have a question.  
13 This is Brandon. More for the broader APHOPs  
14 panel. CPT 64568, what else is in there besides  
15 codes like this that if we updated the rate on  
16 this code, there would be other procedures in  
17 there that have nothing to do with this, with  
18 Vivistim, that would be increased as well?

19 DR. HAMBRICK: Is that directed? Oh,  
20 go ahead.

21 DR. MANAKER: Let's just say the CPT  
22 code is specific that it's for open implantation

1 of any cranial nerve neurostimulator electrode  
2 system and pulse generator. So there's going to  
3 be -- in that, there are going to be vagal,  
4 hypoglossal. Those would be the two big ones.

5 And any device that would be  
6 stimulating either of those nerves would be  
7 suitable for that specific CPT code. So it's  
8 really a matter of affiliation. It's an old  
9 code that has been in effect since 2011.

10 MR. CARLSON: Dr. Manaker, I just want  
11 to add one piece. There is -- hypoglossal nerve  
12 stimulation has its own independent set of codes  
13 for that procedure.

14 DR. MANAKER: Yes.

15 MR. CARLSON: So CPT 64568 is used  
16 primarily for vagus nerve stimulation.

17 DR. MANAKER: Yeah, that's correct. I  
18 forgot there was a separate one for the  
19 hypoglossal.

20 DR. HAMBRICK: Any other questions for  
21 Mr. Carlson? And I'll ask for the audience  
22 questions at the end of the grouping.

1                   Next, we'll hear from Seamus Jackson.

2                   MR. JACKSON: Good afternoon, members  
3 of the panel. My name is Seamus Jackson, and I  
4 represent ZOLL Respicardia. I'm here on behalf  
5 of the Neuromodulation Payment Policy, or the  
6 NPP Coalition, of which both Gary and Brian, and  
7 their organizations, are members. Next slide,  
8 please.

9                   So, the NPP Coalition was formed in  
10 2019, and it brings together five medical  
11 technology companies focused on stimulation  
12 therapies.

13                  Importantly, these therapies address  
14 small and underserved patient populations in a  
15 wide range of very different clinical areas. You  
16 can see some of them listed on the slide. Many  
17 of these therapies are used for patients who  
18 have exhausted other treatment options. Next  
19 slide, please.

20                  So, our ask today is that the panel  
21 reaffirm last year's recommendation to CMS to  
22 create a new level 6 neurostimulator and related

1 services APC effective January 1, 2026. So, as  
2 referenced already, last year, this panel made  
3 the same recommendation. CMS stopped short of  
4 creating the level 6 APC.

5 However, they did act by moving two of  
6 the technologies back into New Tech APC 1580,  
7 where they continue to be assigned in the  
8 proposed rule for 2026.

9 This does temporarily resolve access  
10 challenges for the two technologies that were  
11 moved, but as mentioned, it previously  
12 perpetuated the substantial underpayment for  
13 64568, which remains in level 5, and it also  
14 continues the long-term uncertainty about where  
15 all of these technologies will be assigned in  
16 the future without an adequate APC payment band.

17 So, for those of you who have heard it,  
18 our rationale remains consistent with last year  
19 that there's a substantial payment gap between  
20 the current level 5 payment rate and the  
21 resources required to offer these technologies,  
22 and this negatively impacts Medicare beneficiary

1 access.

2           Creating a new level 6 APC is  
3 consistent with CMS's APC payment methodology  
4 and is especially relevant as the IPO list is  
5 being phased out, and there are several other  
6 simulation technologies that will require  
7 reasonable APC assignment. Next slide, please.  
8 So, in the proposed rule, CMS commented that the  
9 OPPS is a prospective payment system and that  
10 over and underpayments will average out, and we  
11 contend that this is not how hospitals operate  
12 when evaluating the financial viability of  
13 procedures, particularly those that are high-  
14 cost and those that are used in different  
15 clinical areas.

16           So, our evidence for this is twofold.  
17 First, hospitals make decisions to offer these  
18 procedures at the procedure level. Hospitals do  
19 not look to average out the financial impact  
20 across the specialties that manage these very  
21 different diseases.

22           And second, the MPP technologies, or

1 those referenced by this coalition, are only  
2 offered by highly specialized facilities. Only  
3 about 15% of the hospitals that perform level 5  
4 procedures also offer the MPP coalition  
5 technologies.

6 And so, the substantial underpayment of  
7 \$10,000 to \$20,000 per patient associated with  
8 these technologies will be absorbed  
9 disproportionately by the 15% of specialty  
10 centers that choose to offer them. This payment  
11 gap will certainly limit Medicare beneficiary  
12 access. Next slide, please.

13 So, as it stands today, APC 5465 is the  
14 highest payment level for stimulator-related  
15 procedures. The payment rate is driven by four  
16 established high-volume procedures that make up  
17 99% of the claims and, as proposed, CPT 64568  
18 has a GMC of over \$47,000, which is over \$15,000  
19 higher than the payment rate. This creates a  
20 substantial per-patient loss that the hospital  
21 will need to absorb. And next slide, please.

22 So, while this issue only impacts 64568



1 under CMS's current proposal for calendar year  
2 2026, it will negatively impact other coalition  
3 technologies when their temporary assignments to  
4 New Tech APC terminate, unless a level 6 is  
5 created.

6 So, as you can see in the graphic, the  
7 green dots represent other technologies  
8 temporarily assigned to New Tech APC that have  
9 total costs consistent with 64568 and will  
10 create very similar access challenges if brought  
11 into the existing APC 5465.

12 We contend that a level VI 6 is the  
13 most appropriate way to ensure permanent and  
14 appropriate payment for all coalition  
15 technologies --

16 MR. BAILEY: Pardon me. One minute  
17 remaining.

18 MR. JACKSON: -- sure -- while also  
19 facilitating appropriate payment as other  
20 stimulation technologies migrate off the IPO  
21 list. Last slide, please.

22 So in closing, I want to thank the

1 panel for your time and consideration. We ask  
2 that the panel, consistent with last year,  
3 recommend CMS create a new level 6 APC,  
4 effective for calendar year 2026.

5 And in summary, the proposed change  
6 addresses the gap in payment between the GMC of  
7 level 5 and the coalition procedure  
8 requirements. It provides hospital payment  
9 stability and consistency. It allows for a  
10 smoother transition for procedures moving off  
11 the IPO list. And most importantly, it ensures  
12 continued Medicare beneficiary access to these  
13 technologies.

14 Thank you very much for your time, and  
15 please let us know if there are any questions.  
16 Thank you.

17 DR. HAMBRICK: Are there any questions  
18 for the MPP coalition?

19 MS. DAVIS: There are no raised hands  
20 at this time.

21 DR. HAMBRICK: Thank you. Are there  
22 any in the chat?

1 MS. CESNIK: No questions in the chat.

2 DR. HAMBRICK: Wait, wait, wait. Okay.

3 In the chat. Okay.

4 Now, panel members who want to -- were  
5 you trying to get in, Dr. Tettelbach?

6 DR. TETTELBACH: Yeah, I lost signal  
7 for a minute. I'm back.

8 DR. HAMBRICK: Okay. Blake Dirksen, go  
9 ahead, please.

10 MR. DIRKSEN: Great, thank you. Not  
11 sure who to direct this to, the speakers, but I  
12 am curious why this MPP technology as a  
13 neurostimulator is significantly more expensive  
14 than other neurostimulator technologies?

15 MR. JACKSON: I'm happy to take a crack  
16 at that one, and then we can add others as well.  
17 I think the neurostimulation technologies serve  
18 small patient populations. They take a lot of  
19 resources to bring to market.

20 They're cutting-edge. They take years  
21 to develop. And for that reason, the resources  
22 required to offer them are higher than for

1 others.

2 Gary, Brian, anything to add?

3 MR. DELHOUGNE: Yeah, Seamus, I was  
4 just going to reiterate exactly what you  
5 mentioned around the small and distinct patient  
6 populations, not like the high-volume procedures  
7 that we see within level 5, those dominant  
8 procedures, you know, 5, 10, or more thousand,  
9 you know, OPPS claims versus ours in the  
10 hundreds.

11 MR. CARLSON: Yeah, I agree as well.

12 MR. DIRKSEN: Thank you.

13 DR. HAMBRICK: Okay. Any other  
14 questions from panel members? Once again, are  
15 there any questions from the audience? Anybody  
16 raised hands, Ms. Davis?

17 MS. DAVIS: Currently, there are no  
18 raised hands.

19 DR. HAMBRICK: Thank you. How about in  
20 the chat?

21 MS. CESNIK: No questions in the chat.

22 DR. HAMBRICK: Thank you.

1 Does the panel have a recommendation  
2 with respect to any of the presentations? And  
3 if specific to one, please tell us which one it  
4 is so we can get it accurately for them there.  
5 Well, if it's all of them, then that's fine,

6 too. MS. ARTIGUE: I'd like to make a  
7 recommendation that will impact all the  
8 presentations. Similar to the recommendation we  
9 made last year, I would like to recommend that  
10 CMS create a level 6 neurostimulator and related  
11 services APC, and consider placing code 64568  
12 into this new level 6 APC.

13 DR. MANAKER: Second.

14 DR. HAMBRICK: Any discussion? All  
15 those in favor, signify by saying aye.

16 (Chorus of aye.)

17 DR. HAMBRICK: Opposed, nay? Any  
18 extensions? Are there any more recommendations  
19 from the panel with regard to these  
20 presentations? Okay. Thank you all.

21 We will now go on to APC Assignment for  
22 Urge Urinary Incontinence Procedure because we

1 did the Skull-Mounted before lunch. Okay.

2 Nate Vercauteren from the Division of  
3 Outpatient Care will present for CMS, and Steven  
4 Siegel, Carla Monacelli, and Jolayne Devers will  
5 present for Neuspera. Thank you.

6 MR. VERCAUTEREN: Hi, everyone. My  
7 name is Nate Vercauteren and I'll cover the CMS  
8 overview and background information for  
9 Neuspera's presentation. Neuspera's request is  
10 to remove the E1 status indicator from CPT code  
11 0786T and assign CPT code 0786T to APC 5464,  
12 which is a level 4 neurostimulator and related  
13 services.

14 Effective January 1, 2024, the CPT  
15 editorial panel separated integrated from  
16 nonintegrated or traditional sacral  
17 neurostimulator procedure by establishing a new  
18 CPT code, 0786T, to report procedures using  
19 integrated sacral neurostimulator devices, while  
20 existing CPT code 64590 was updated to reflect  
21 the use of traditional technology.

22 0786T was assigned to APC 5463, level 3

1 neurostimulator and related procedures.  
2 Effective January 1, 2025, after consideration  
3 of public comments received in response to the  
4 calendar year 2025 OPPS proposed rule, we  
5 assigned CPT code 0786T from APC 5463 to status  
6 indicator E1, which indicates a nonpayable  
7 status by Medicare when submitted on outpatient  
8 claims to any outpatient bill type.

9 This reassignment occurred because, at  
10 that time, no FDA-approved integrated sacral  
11 neuromodulation system existed. In the calendar  
12 year 2026 OPPS ASC proposed rule, addendum B, we  
13 propose to continue to assign CPT code 0786T to  
14 status indicator E1. This concludes my  
15 presentation. Thank you.

16 DR. HAMBRICK: Thank you.

17 You may go ahead, Neuspera.

18 MS. DEVERS: Thank you. My name is  
19 Jolayne Devers. I'm a consultant to Neuspera,  
20 and joining me today is Dr. Steven Siegel, Chief  
21 Medical Officer from Neuspera. Next slide.

22 Our request today is for payment

1 assignment for CPT code 0786T. By way of  
2 background, sacral nerve modulation CPT codes  
3 had a revamp from the CPT editorial panel that  
4 became effective January 1, 2024. Specifically,  
5 the panel did a realignment and defined  
6 integrated and nonintegrated systems.

7 What happened as a result was that they  
8 revised CPT code 64590 to describe nonintegrated  
9 systems that required tunneling and connection  
10 to a lead, in other words, two components, and  
11 then single components were defined as  
12 integrated systems, and they created CPT code  
13 0786T.

14 At the time, Neuspera was not part of  
15 the application. It was just a broader  
16 application that went through the panel.

17 Today, 0786T has an E1 status  
18 indicator. Initially, it was assigned to a  
19 level 3 neurostimulator and related services  
20 APC, and we believe that was an error  
21 potentially based on a different FDA-cleared  
22 Neuspera device that they have for chronic pain.



1           It has never been commercialized but  
2       would appropriately, if being used, be reported  
3       using 64596. As a result, Neuspera approached  
4       CMS and requested the change to the E1 status  
5       indicator.

6           They were not yet FDA-authorized, and  
7       there were no other devices on the market, so  
8       there really wasn't a need to have payment  
9       assignment at that time. Today, we're here to  
10      ask that the HOP panel request CMS remove the E1  
11      status indicator and assign CPT code 0786 to a  
12      level 4 APC, 5464.

13          This is based on clinical homogeneity  
14      because it creates alignment with the other UUI  
15      procedures that include both integrated and non-  
16      integrated devices that are actually both  
17      approved by the FDA and not all of them are  
18      approved by the FDA, as well as resource  
19      similarity.

20          The Neuspera system itself, although it  
21      treats UUI, was FDA PMA approved in June of this  
22      year. It has an ASP of 17.5 and a total

1 hospital cost of \$21,000. Next slide.

2 This is just a representation of the  
3 various UUI procedures and the corresponding CPT  
4 codes. So you will see that all of these  
5 procedures, including Neuspera, are targeting  
6 the patient population of UUI, include  
7 stimulation of either the tibial or the sacral  
8 nerve.

9 You'll see that there's a variety of  
10 devices in this category and our proposal that  
11 are either PMA approved, such as ours, and that  
12 by Medtronic in 1997, as well as non-approved  
13 devices.

14 Specifically pointing out Coloplast,  
15 they will have a 0988T code effective January  
16 1st of 2026. They are not yet FDA-approved.  
17 Along with the other codes of 0817T and 0816T,  
18 which include approved and non-approved devices.

19 All of the integrated devices are  
20 included in this level 4, as well as the  
21 traditional systems that include both an IPG and  
22 a lead placement. You'll see here from a

1 procedural perspective, there are different  
2 deployments through cannulas and using either  
3 fluoroscopic or ultrasound guidance.

4 Some of the therapies require and  
5 invoke motor sensory response during the  
6 procedure. And there are different levels and  
7 different kinds of fixation that occur with the  
8 various designs of each technology. Next slide.  
9 So we're asking today again that 0786T be  
10 assigned to APC 5464 --

11 MR. BAILEY: Pardon me. You have one  
12 minute remaining.

13 MS. DEVERS: Thank you. -- based on  
14 clinical homogeneity, creating alignment with  
15 other UUI procedures, as you can see here in our  
16 chart, as well as resource homogeneity. Being  
17 that the Neuspera system is a \$17,500 device  
18 with total hospital costs of \$21,000.

19 You'll see that alignment here within  
20 the current fee schedule, fitting in nicely with  
21 5464 at a payment rate of \$21,444. Next slide.

22 So again, our request is to first

1       remove the E1 status indicator, and then assign  
2       0786T to level 4 neurostimulators and related  
3       services based on clinical and resource  
4       homogeneity.

5               Thank you.

6               DR. HAMBRICK: Thank you. Are there  
7       any questions for the presenter from the panel?

8               MS. DAVIS: Currently, there are no  
9       raised hands.

10              DR. HAMBRICK: Thank you. Anything in  
11       the chat?

12              MS. CESNIK: Currently, there are no  
13       questions in the chat.

14              DR. HAMBRICK: Thanks. Any  
15       recommendations from the panel with respect to  
16       this presentation?

17              DR. DAWSON: Yes, I will recommend that  
18       CMS remove the E1 status indicator and assign  
19       the CPT code 0786T to APC 5194.

20              DR. MANAKER: Second.

21              DR. HAMBRICK: I think we need to  
22       clarify the APC. Page 139 is 5464, and some of

1 the presentation materials have said 5194. So  
2 what is the request from the presenter?

3 DR. DAWSON: 5464, level 4  
4 neurostimulators and related services.

5 DR. HAMBRICK: Okay. Then I will add  
6 it to say that -- to move it to CPT 5464. Okay.  
7 All right. So 0786T to APC 5464. Is that  
8 correct?

9 DR. DAWSON: That is correct. Thank  
10 you.

11 DR. HAMBRICK: Okay. Is there a  
12 second?

13 DR. MANAKER: Yes, second.

14 DR. HAMBRICK: Okay. Discussion?

15 MS. ARTIGUE: This is Jennifer Artigue.  
16 Just to make sure that removing the E1 status  
17 indicator is also included in that  
18 recommendation.

19 DR. HAMBRICK: Okay.

20 DR. DAWSON: Yes, I include --

21 DR. HAMBRICK: I think you said that at  
22 first.

1 DR. DAWSON: I did, yes. Remove the E1  
2 status indicator.

3 MS. ARTIGUE: Just to make sure. I  
4 think you did say that. Yes, you did say that.

5 All those in favor, say aye.

6 (Chorus of aye.)

7 DR. HAMBRICK: Opposed, nay? Any  
8 abstentions? Thank you very much.

9 It's not break time, so now we're going  
10 to move on to the IPO list and various APC  
11 requests. Gina Aughenbaugh will give the docs  
12 overview for CMS. Then we have two  
13 presentations: one from Kirsten Tullia from  
14 AdvaMed, and one from Yajuan Lu from Boston  
15 Scientific.

16 We'll follow the same procedure after  
17 the CMS presentation. We'll have each presenter  
18 present, and we'll have a discussion about their  
19 presentation immediately following it.

20 So, if you can go ahead, Ms.  
21 Aughenbaugh, thank you very much.

22 DR. MANAKER: Hang on, Dr. Hambrick. I

1       need to recuse myself from any votes for this  
2       because of an issue with Boston Scientific. I  
3       have learned that there is a payment exceeding  
4       the de minimis CMS amount available on open  
5       payments.

6               My friends and colleagues in industry  
7       know I do not accept anything from industry, so  
8       this must have been an allocation from some  
9       event I attended at one or another society  
10      meeting, but because it exceeds the de minimis  
11      amount, I need to recuse myself from any voting.

12             DR. HAMBRICK: Thank you, Dr. Manaker.  
13      And that would be for both Boston Scientific  
14      presentations, correct?

15             DR. MANAKER: Correct.

16             DR. HAMBRICK: Okay. Thank you.

17             You can go ahead, Ms. Tullia. I'm  
18      sorry. We didn't have the CMS. I'm moving right  
19      along here. Aughenbaugh, thank you.

20             MS. AUGHENBAUGH: Good afternoon. My  
21      name is Gina Aughenbaugh. I am an analyst in  
22      the Division of Outpatient Care at CMS. I will

1 be providing a summary on the inpatient-only  
2 list, reconfiguring APCs and comments to  
3 specific APCs on the comment letter submitted on  
4 behalf of AdvaMed and Boston Scientific.

5 Please note, Boston Scientific only  
6 provided comments on coronary therapeutic  
7 services and procedures, which will be specified  
8 upon discussion.

9 Our first topic is on the inpatient-  
10 only list, often referred to as the IPO list.  
11 The IPO list was established with the  
12 implementation of the OBPS in the calendar year  
13 2000 OBPS ASC final rule with comment period.

14 The IPO list identifies services for  
15 which Medicare will only make payments when the  
16 services are furnished in the inpatient hospital  
17 setting because of the invasive nature of the  
18 procedure, the underlying physical condition of  
19 the patient, or the need for at least 24 hours  
20 of postoperative recovery time or monitoring  
21 before the patient can safely be discharged.

22 Designation of a service as inpatient-only



1 does not preclude the service from being  
2 furnished in a hospital outpatient setting, but  
3 means that Medicare will not make payments for  
4 the services if it is furnished to a Medicare  
5 beneficiary in the hospital outpatient setting.

6 In the calendar year 2026 OBPS ASC  
7 proposed rule, CMS proposed to eliminate the IPO  
8 list over three years, beginning with removing  
9 285 codes, most of which are musculoskeletal  
10 procedures.

11 There are three recommendations from  
12 AdvaMed. The first two are about collaborating  
13 with stakeholders on rate-setting methodology,  
14 payments for procedures removed from the IPO  
15 list, and APC assignments. The last  
16 recommendation is to monitor any changes that  
17 the site of service may have on patient outcomes  
18 and safety.

19 The second topic regards reconfiguring  
20 ambulatory payment classifications, also known  
21 as APCs. AdvaMed will be making requests  
22 regarding complexity adjustments, which will be

1 addressed in upcoming presentations. Therefore,  
2 we are holding discussions on this topic until  
3 after those presentations.

4 The last topic is on specific APCs like  
5 noninvasive arterial plaque analysis, radiation  
6 therapy, first carpometacarpal total joint  
7 arthroplasty, and coronary therapeutic services  
8 and procedures.

9 Please note that while most of this  
10 overview is for AdvaMed, Boston Scientific did  
11 have the same recommendation on APC 5194 for  
12 coronary therapeutic services and procedures,  
13 which is our fourth topic being covered.

14 First, starting with noninvasive  
15 arterial plaque analysis. In 2022, there were  
16 four new CPT-3 codes: 0710T, 0711T, 0712T, and  
17 0713T, which were established to report  
18 noninvasive arterial plaque analysis. This is a  
19 SAS imaging service that uses data from CT and  
20 geography to produce clinical information about  
21 arterial plaque for providers.

22 As we will hear in the presentation,

1 they are requesting that CMS reassign one of  
2 these codes, specifically CPT code 0712T, to a  
3 different APC. CPT code 0712T is currently  
4 assigned to APC 5521, which is a level 1 imaging  
5 without contracts, which has a payment rate of  
6 approximately \$88.

7 They are requesting that CMS reassign  
8 CPT code 0712T to a new technology, APC 1511,  
9 with a payment rate of \$950.50, using CPT code  
10 0625T as a crosswalk code. The long descriptors  
11 for CPT code 0712T and their comparatory code  
12 0625T are located on the slide. This concludes  
13 my brief overview of this APC-specific issue.

14 Next slide, please. AdvaMed's next  
15 request involves the topic of radiation therapy.  
16 In September of 2024, the CPT editorial panel  
17 approved several changes to the codes describing  
18 radiation oncology treatment delivery,  
19 specifically establishing a technic-agnostic  
20 family of codes and bundling the imaging into  
21 all three services. The panel approved  
22 revising the descriptors for CPT codes 77402,

1 77407, and 77412 to include intensity modulation  
2 radiation therapy, IMRT, to approve deleting the  
3 two CPT codes that currently describe IMRT,  
4 which are CPT codes 77385 and 77386.

5 For calendar year 2026, we are  
6 proposing to maintain the APC assignments for  
7 CPT codes 77402, 77407, and 77412. CPT code  
8 77402 is assigned to APC 5621, a level 1  
9 radiation therapy.

10 Then, CPT codes 77407 and 77412 are  
11 assigned to APC 5622, level 2 radiation therapy.  
12 AdvaMed is requesting to reassign CPT codes  
13 77407 and 77412 to higher APCs to account for  
14 the claims data of the deleted IMRT codes.

15 They are specifically recommending  
16 reassigning CPT code 77407 to APC 5623, which is  
17 a level 3 radiation therapy. And then, CPT  
18 codes 77412 to APC 5624, which is a level 4  
19 radiation therapy. This concludes my brief  
20 overview of the APC-specific issue. Next slide,  
21 please.

22 The third topic involves first

1       carpometacarpal total joint arthroplasty, for  
2       which the CPT editorial panel established the  
3       CPT code 1003T with an effective date of January  
4       1st of 2026.

5               This code was created to report  
6       arthroplasty of the first carpometacarpal joint  
7       with distal, trapezial, and proximal first  
8       metacarpal prosthetic replacement.

9               For calendar year 2026, we propose to  
10       assign CPT code 1003T to APC 5114, which is a  
11       level 4 musculoskeletal procedure with a  
12       proposed payment rate of approximately \$7,500.

13              The recommendation that we will hear  
14       shortly from AdvaMed is for CMS to assign CPT  
15       code 1003T to APC 5116, a level 6  
16       musculoskeletal procedures with a proposed  
17       payment rate of approximately \$18,000. AdvaMed  
18       contends that this procedure described by CPT  
19       code 1003T is more similar to other arthroplasty  
20       procedures in APC 5116.

21              Lastly, we have a discussion on  
22       coronary therapeutic services and procedures,

1 which was written by AdvaMed as well as Boston  
2 Scientific. CPT codes 92X01 and 92X02 are new  
3 codes that will be effective January 1st of  
4 2026. These describe cardiac procedures  
5 such as stent placement with angioplasty and a  
6 procedure that includes any combination of stent  
7 placement, atherectomy, and angioplasty.

8 For calendar year 2026, we proposed to  
9 assign both new CPT codes to APC 5193, which  
10 falls into level 3 endovascular procedures with  
11 a proposed payment rate of \$11,300. Both  
12 parties are requesting to reassign CPT codes  
13 92X01 and 92X02 to APC 5194, which is a level 4  
14 endovascular procedure with a proposed payment  
15 rate of almost \$18,000.

16 This concludes my overview of AdvaMed  
17 and Boston Scientific presentations.

18 DR. HAMBRICK: Are there any questions  
19 for Ms. Aughenbaugh?

20 Mr. Dirksen?

21 MR. DIRKSEN: Following Dr. Manaker's  
22 lead, I work in radiation oncology, so I will be

1       recusing myself from any voting on the radiation  
2       oncology APCs, but welcome any questions from my  
3       colleagues.

4               DR. HAMBRICK: Thank you.

5               Any more comments before Ms. Tullia?

6       No questions. All right.

7               Why don't you go ahead, Ms. Tullia.

8               MS. TULLIA: Great. Thank you.

9               And thank you very much, Gina. I  
10       realize that was a lot. I'm going to try and  
11       set some kind of record for covering topics as  
12       quickly as humanly practicable.

13               So, to begin with the IPO list  
14       comments, AdvaMed has commented previously  
15       around the elimination of the IPO list, with our  
16       focus really being around the reasonable  
17       placement of procedures as they are moved into  
18       the outpatient setting of care.

19               One of our biggest contentions with the  
20       proposal as presented in this year's proposed  
21       rule is that there is no specified process for  
22       how CMS is going to place procedures in APCs as

1       they are transitioned, which is particularly  
2       important as we're looking at well over a  
3       thousand procedures that will be moving over a  
4       period of three years.

5               Just looking at the 285 procedures that  
6       were identified for this year, we're seeing  
7       things, particularly in the musculoskeletal  
8       space, as many of the codes reside here, where  
9       we have primary procedures and revisions being  
10      assigned to the same APC, despite the fact that  
11      revisions tend to be significantly more  
12      resource-intensive, as well as more clinically  
13      complex for patients to undergo.

14             And we would like to see CMS provide a  
15      proposal for exactly how they plan to distribute  
16      these codes across the multiple APCs that  
17      they'll be going into, as well as looking at the  
18      total impact of the cost in these different  
19      changes in the outpatient procedures, and  
20      focusing on the impact on budget neutrality  
21      associated with this transition.

22             One of the important pieces that we did



1 want to highlight is that there is data within  
2 the CMS system on cost for these procedures,  
3 specifically from the inpatient system.

4 We are working with consultants now to  
5 look at opportunities for how to best crosswalk,  
6 or a recommendation on how to best crosswalk  
7 between inpatient and outpatient, looking at  
8 removing different components of the inpatient  
9 cost to better reflect what a procedure could  
10 cost in the outpatient setting.

11 We believe this would better ensure  
12 that patients maintain access to these  
13 procedures as they are transitioned to the  
14 outpatient, rather than creating a perverse  
15 incentive to continue providing in the inpatient  
16 regardless of the outpatient accessibility.

17 We would also like to flag that we have  
18 some concerns around unintended consequences  
19 associated with rapid elimination of the IPO  
20 list absent these modifications to look at cost  
21 and payment modifications, specifically that  
22 there is a huge focus on ensuring that no harm

1 comes to patients resulting from the removal of  
2 the IPO list in CMS's own proposal.

3 One of the examples here was exempting  
4 short stays from RAC audits. However, those are  
5 only used in the fee-for-service system. That  
6 doesn't apply to the Medicare Advantage program.  
7 And so we would like to ensure that there is a  
8 better accounting for how these impacts will be  
9 manifest across the other entities that we know  
10 rely upon the inpatient-only list.

11 We also have feedback from our members  
12 indicating that private insurers frequently look  
13 to the IPO list as a component of how they are  
14 making medical policy.

15 And that there is a tendency for when  
16 procedures are removed from the IPO list for the  
17 outpatient setting to become the preferred or  
18 sole setting of care that a procedure is  
19 provided in, which we believe is going to create  
20 issues with access to care for patients who may  
21 be more clinically complex than a patient who  
22 would be best served by being in the outpatient

1       setting.

2               So ultimately, as Gina mentioned, what  
3       we would like to see CMS do is provide a more  
4       clear and concise, and repeatable process for  
5       how procedures that are removed from the  
6       inpatient-only list will be assigned to APCs, to  
7       provide an opportunity for comment on  
8       modifications to those for the 285 procedures  
9       that are currently being proposed for removal  
10      from the IPO list.

11              As well as some consideration for  
12      procedures such as total heart replacement and  
13      others, which might not be appropriate for  
14      performance in the outpatient setting at any  
15      point due to the clinical nature of those  
16      procedures.

17              Moving to the clinical proposals.

18              MR. BAILEY: Pardon me. One minute  
19      remaining.

20              MS. TULLIA: Oh, of course. Okay. So,  
21      unfortunately, I have a series of proposals.  
22      Obviously, we do have non-invasive arterial

1 plaque analysis, which is 0712T. The issue here  
2 being that images assessed under this code are  
3 obtained from CTA and include contrast, so they  
4 should not be included in a non-contract APC.  
5 We therefore request removal or replacement in  
6 APC 1511.

7 Moving to radiation therapy, we believe  
8 that the issue here is IMRT volume was not  
9 included, and the costs were not included in the  
10 APC calculation, which resulted in misplacement.

11 And we are recommending the resolution  
12 suggested by the American Society for Radiation  
13 Oncology, which is two of the two codes, as Gina  
14 mentioned in her summary. And then for the  
15 total joint arthroplasty, I wanted to flag that  
16 while historically other hand and wrist surgical  
17 procedures are frequently assigned to APC 5114,  
18 they're not total joint reconstructions.

19 And so in this case, we would like to  
20 look at the complexity of the prosthesis itself,  
21 the detailed preparation of multiple bones, and  
22 the higher cost articulating implant involved in

1 the first carpometacarpal total joint.

2 MR. BAILEY: That's time.

3 MS. TULLIA: Okay. Understandable. I  
4 had a very long comment letter this year.  
5 I appreciate your time.

6 DR. HAMBRICK: Thank you. Are there  
7 any questions for Ms. Tullia from the panel?

8 Are there any hands raised in queue,  
9 Ms. Davis?

10 MS. DAVIS: Currently, there are no  
11 raised hands.

12 DR. HAMBRICK: Thank you.

13 Are there any questions in chat or at  
14 this time?

15 MS. CESNIK: No questions. No  
16 questions in the chat.

17 DR. HAMBRICK: Thank you.

18 We'll, as I said, discuss at the end of  
19 the second presentation.

20 If you'd like to go ahead, Yajuan Lu.

21 MS. LU: Yajuan. Thank you very much.  
22 Making sure I'm coming through clearly?

1 DR. HAMBRICK: Yes, we can hear you.

2 MS. LU: Great. Well, thank you very  
3 much for the opportunity to present on this  
4 subject. My name is Yajuan Lu, Director of  
5 Health Economics and Market Assets at Boston  
6 Scientific.

7 Together with me on this call is also  
8 Dr. Modolo, Interventional Cardiologist and  
9 Senior Medical Director at Boston Scientific.  
10 Next slide, please.

11 In this year's rule, CMS reviewed the  
12 list of the CPT codes that are to take effect on  
13 January 1st, 2026, and proposed their APC  
14 assignments.

15 And among them are the two PCI codes  
16 shown on this slide, specifically 92X01, which  
17 describes complex coronary stenting in multiple  
18 distinct lesions or bifurcation lesion, and code  
19 92X02, describing complex chronic total  
20 occlusion, combined antigrade and retrograde  
21 approaches.

22 CMS proposed assigning both codes to

1 APC 5193, considering the clinical complexity  
2 associated with these codes and also the higher  
3 resource utilization associated. Boston  
4 Scientific's proposal is for the panel to invite  
5 CMS to assign both of these codes to the next  
6 higher level of APC, which is 5194. Next slide,  
7 please.

8 So now I'm going to invite Dr. Modolo  
9 to walk through the clinical complexity  
10 represented by both codes.

11 Dr. Modolo?

12 DR. MODOLO: Thanks. Thanks a lot,  
13 Yajuan. So what I'm going to do here is just  
14 talk about the medical aspects of both  
15 procedures, the stenting and CTO, talking about  
16 the difference between the existing codes and  
17 our non-complex stenting and CTO, and the  
18 complex stenting and complex CTO.

19 For a regular non-complex stenting,  
20 basically you have a single artery, one lesion,  
21 a more straightforward procedure, as opposed to  
22 a complex stenting, where usually you have a

1 multiple-vessel disease with two or more  
2 lesions, usually involving bifurcation.

3 And/or left main coronary artery  
4 disease, or even a severely calcified lesion,  
5 where you will need more resources, more time,  
6 and basically in those procedures of complex  
7 stenting, you will have increased procedural  
8 time.

9 You will have a higher risk to the  
10 patient because radiation exposure increases,  
11 you use more contrast media, and that kidney is  
12 not a fan of contrast media, so the patient will  
13 likely have more acute kidney injury, which will  
14 lead to prolonged hospitalization.

15 There will be increased resource  
16 utilization because these patients will more  
17 likely need LV support devices, more physicians  
18 in the room, like anesthesiologists, and  
19 multiple devices will probably be used, not only  
20 drug-eluting stents and balloons, but probably  
21 the attractive devices such as imaging and  
22 lesion prep, because those are complex lesions.



1                   Now, let's focus on the right, the  
2                   complex CTO part, and how it differs from the  
3                   non-complex existing code for CTO. The non-  
4                   complex CTO basically is what I already told on  
5                   the left, because it's an anti-grade approach,  
6                   but with a chronic total occlusion.

7                   Now, for a complex CTO, you're heading  
8                   to the anti-grade approach, a retrograde  
9                   approach, and it's important to say that a  
10                  retrograde approach already starts the procedure  
11                  with two catheters, two sites of access in the  
12                  patient, which increases risk, and both  
13                  catheters have contrast media being injected,  
14                  and all the devices.

15                  Because for a retrograde CTO, you have  
16                  to go from one site to the heart to the other,  
17                  and when you pass through collaterals, you're  
18                  more likely to cause complications, and the most  
19                  seen is perforation, which can lead to  
20                  tamponade, and it's a big deal to the patient.  
21                  So, retrograde is inherently more complex.

22                  MR. BAILEY: Pardon me. One minute

1 remaining.

2 DR. MODOLO: Okay. There is more risk  
3 to the patient, procedural time is increased,  
4 and multiple guide wires and microcatheters.

5 For the sake of time, I'll pass it back  
6 to Yajuan to wrap us up.

7 MS. LU: Thank you, Dr. Modolo. As you  
8 just presented, both of these codes represent a  
9 higher level of the complexity adjustment  
10 compared to the existing codes, which are  
11 currently assigned already to APC 5193 and 5194.

12 We want to particularly note that for the  
13 CTO procedure, one of the existing codes is  
14 C9607, describing CTO with DS, which represents  
15 76% of all the CTO procedures in the outpatient  
16 setting, is already assigned to APC 5194, and  
17 the new code 9202 represents a higher level of  
18 complexity.

19 Therefore, our conclusion is that CMS  
20 should propose both of the new codes, 9201 and  
21 9202, to a higher level of APC, which is 5194.  
22 Thank you very much.

1 DR. HAMBRICK: Thank you.

2 Are there any questions for Boston  
3 Scientific?

4 Is there anybody in queue, Ms. Davis?

5 MS. DAVIS: There are no raised hands.

6 DR. HAMBRICK: And in the chat, any  
7 questions?

8 MS. CESNIK: No questions in the chat.

9 DR. HAMBRICK: All right. Thanks.

10 All right. Let's see if there are any  
11 recommendations with respect to either  
12 presentation from panel members.

13 MS. CESNIK: There's a hand raised in  
14 the attendees.

15 DR. HAMBRICK: Thank you.

16 MS. ARTIGUE: This is Jennifer. I'd  
17 like to make a recommendation, please.

18 DR. HAMBRICK: Okay.

19 And we'll do you next, Mr. Dirksen. Go ahead.

20 MS. ARTIGUE: I apologize. I got cut  
21 in front of Derek again. I'm sorry.

22 So here's my recommendation. So CMS

1       -- the APC panel recommends that CMS assign new  
2       CPT codes 9201 and 9202 to APC 5194.

3               DR. HAMBRICK: Okay. Is there a  
4       second?

5               MR. FAZIO: Second.

6               DR. HAMBRICK: Discussion? All those  
7       in favor, signify by saying aye.

8               (Chorus of aye.)

9               DR. HAMBRICK: Opposed nay? And we  
10       have one abstention. Is that correct, Dr.  
11       Manaker?

12               DR. MANAKER: I abstain. Thank you.

13               DR. HAMBRICK: Okay. All right.

14       Motion passes.

15               Mr. Dirksen.

16               MR. DIRKSEN: Thank you. Yeah, I just  
17       want to -- I'm not going to make a motion  
18       because I abstain, but just a little bit of  
19       context on the APC placements for radiation  
20       therapy.

21               With the new treatment codes that have  
22       been generated, over two-thirds of the treatment

1 delivery codes are currently already in level 3  
2 APC 5263, but with the creation of the new code,  
3 those all end up in 6222, and we think that's an  
4 oversight because the IMRT codes maybe weren't  
5 included.

6 Just kind of want to make sure we  
7 circle back to that topic, and I'll welcome  
8 questions from anybody if they have them.

9 DR. HAMBRICK: Okay, that's a comment  
10 for the record. You will be abstaining from  
11 voting, and it was, as you feel, on the nature  
12 of the service as opposed to the APC placement  
13 or anything like that, correct?

14 MR. DIRKSEN: No, I think the APC  
15 placement should be corrected as recommended by  
16 AdvaMed.

17 DR. HAMBRICK: Getting kind of close  
18 there, Mr. Dirksen. Yeah, yeah.

19 Ms. Trevas has a question. I think she  
20 wants clarification on the recommendation.  
21 Go ahead.

22 MS. TREVAS: That's exactly my

1 question. And I understand that it is not a  
2 recommendation, as you are saying, and also that  
3 you're saying that the codes that are in 5263  
4 are moving to -- I'm sorry. Which ABC code?

5 DR. HAMBRICK: Ms. Artigue has the  
6 recommendation, so let's have her clarify.

7 MS. TREVAS: Okay.

8 DR. HAMBRICK: Mr. Dirksen was making  
9 comments. Okay.

10 Okay, go ahead, Ms. Artigue.

11 MS. ARTIGUE: Yes, mine was in relation  
12 to the Boston Scientific presentation, and it  
13 was -- the proposal was to assign CPP codes 9 to  
14 X01 and 9 to X02 to APC 5194. But just for  
15 clarification, this is not in relation to the  
16 radiation therapy code.

17 MR. DIRKSEN: I apologize. This is  
18 Blake. I jumped to another topic before I think  
19 we had completed your motion. I apologize.

20 MS. TREVAS: No, that's okay.

21 DR. HAMBRICK: Ms. Trevas, did you get  
22 what you needed?

1 MS. TREVAS: Yes, I have Ms. Artigue's  
2 recommendation, and I assume we will move on to  
3 Dr. Dirksen's recommendation next.

4 DR. HAMBRICK: He doesn't have a  
5 recommendation

6 MS. TREVAS: Right. We will move on to  
7 the discussion about Dr. Dirksen's comment next.  
8 Yes? Okay. Thank you.

9 DR. HAMBRICK: Potentially. So, we  
10 have Ms. Artigue. I think we had a second. I  
11 think Ms. Lloyd would like to make a comment.

12 MS. SMITH-LLOYD: I thought we had  
13 voted on that. I have a comment. I have a  
14 recommendation for something else.

15 DR. HAMBRICK: Okay, great. Okay.

16 MS. DAVIS: We do. Yes, there's Wendi  
17 Smith.

18 MS. SMITH: Hi.

19 DR. HAMBRICK: Right. Wendi Smith.  
20 Oh, okay.

21 MS. SMITH: Wow, I'm really going to  
22 confuse you today.

1 DR. HAMBRICK: Yes, you are.

2 So, we have an audience person who  
3 wishes to comment on what? Go ahead, Wendi  
4 Smith.

5 MS. SMITH: Hi, can you hear me? Hello,  
6 can you hear me?

7 DR. HAMBRICK: Yes, yes, we can.

8 MS. SMITH: Hi, this is Wendi Smith  
9 with Health Policy Solutions, and I'm just  
10 curious if the CMS staff can respond to the  
11 question regarding when they looked at proposed  
12 reassignment of the three new treatment delivery  
13 codes, which include not only image guidance,  
14 but also IMRT and if they did, in fact, look at  
15 the deleted IMRT codes and included them in the  
16 relevant new 77407 and 77412.

17 We're just curious if this was an  
18 oversight, and maybe staff can answer that  
19 question. Thank you.

20 DR. HAMBRICK: Okay, let's hold that  
21 for a minute.

22 So, panel, did we vote on Ms.



1 Artigue's recommendation? I don't remember  
2 voting on that. Did we vote on it?

3 MS. SMITH-LLOYD: I don't think we did.

4 DR. HAMBRICK: I thought we had. I  
5 thought we had, but we could go again.

6 MS. TREVAS: This is Dana.

7 DR. HAMBRICK: Yes.

8 MS. TREVAS: Dr. Hambrick? Yes, you  
9 did vote on it, and there were -- yeah, it was  
10 unanimous.

11 DR. HAMBRICK: Okay, great. Thank you.  
12 So, now we can move on to another  
13 topic. Ms. Smith-Lloyd.

14 MS. SMITH-LLOYD: I would like to make  
15 a recommendation based on AdvaMed's proposal. I  
16 recommend CMS reassign CPT code 1003T to  
17 APC5116.

18 DR. HAMBRICK: Okay. Is there a  
19 second?

20 MS. ARTIGUE: I'm not even sure what  
21 that CPT code is. Did we talk about that?

22 MS. SMITH-LLOYD: Ma'am, yeah, that's

1 the new arthroscopic code.

2 MS. ARTIGUE: Okay, gotcha. Thank you.

3 MS. SMITH-LLOYD: And it would align  
4 with the other arthroplasty procedures.

5 DR. DAWSON: Yes, I will second -- This  
6 is Nancy Dawson. I'll second that.

7 DR. HAMBRICK: Okay, discussion? All  
8 those in favor, signify by saying aye.

9 (Chorus of aye.)

10 DR. HAMBRICK: Opposed? Nay? Any  
11 abstentions?

12 DR. MANAKER: I don't think I have to  
13 abstain for this, Dr. Hambrick.

14 DR. HAMBRICK: Okay, thank you.

15 All right. Next recommendation from a  
16 panel member. There was a question raised on  
17 radiation oncology. Does any panel member have  
18 a recommendation who has not abstained on the  
19 radiation oncology code?

20 MS. ARTIGUE: Dr. Hambrick, this is  
21 Jennifer Artigue. I'd like to hear CMS's  
22 response to Ms. Smith's question before making a

1 recommendation.

2 DR. HAMBRICK: Okie dokie.

3 MR. RICE: Sure, this is David Rice. I  
4 can respond. You know, we are aware of those  
5 changes in IMRT. We've heard a lot on this  
6 subject and expect public comment on it for the  
7 final rule. And, of course, we will address  
8 that comment in the final rule.

9 DR. HAMBRICK: Thank you. So, any  
10 recommendations with respect to the radiation  
11 oncology codes? All right. Any recommendations  
12 with respect to anything else on AdvaMed? Okay,  
13 not hearing any.

14 We can move on to a discussion of the  
15 comprehensive APC complexity adjustment. Ms.  
16 Elise Barringer will give us the overview. And  
17 then Ta-Yuan Ho from Boston Scientific will make  
18 a presentation. We'll also review a comment  
19 letter from Johnson & Johnson.

20 Dr. Manaker, would you like to repeat  
21 your previous statements, or do you want to just  
22 say that you're on the record for this

1 particular presentation from Boston?

2 DR. MANAKER: The statement is on the  
3 record, Dr. Hambrick. Thank you very much, and  
4 I will again abstain.

5 DR. HAMBRICK: Thank you.

6 You can go ahead, Ms. Barringer.

7 MS. BARRINGER: Thank you. Hi, I'm  
8 Elise Barringer and I'll be covering the  
9 overview for the Boston Scientific presentation  
10 and the Johnson & Johnson comment letters on  
11 comprehensive or CAPC complexity adjustment  
12 methodology.

13 CAPCs provide a single payment for a  
14 primary source identified by status indicator  
15 J1, packaging payment for adjunctive and  
16 secondary item services and procedures into the  
17 most costly primary procedure on the claim.  
18 Complexity adjustments are used to provide  
19 increased payment for certain comprehensive  
20 services.

21 We apply complexity adjustments by  
22 promoting qualifying paired J1 service code

1 combinations or paired code combinations of J1  
2 services and certain add-on codes from the  
3 originating CAPC to the next higher paying CAPC  
4 in the same clinical family of CAPCs.

5 The criteria for a complexity  
6 adjustment are that a paired combination  
7 represents a complex, costly former version of  
8 the primary service by meeting:

9 (1) A frequency threshold of 25 or more  
10 claims reporting the code combination, and

11 (2) A cost threshold where the  
12 geometric mean cost of all evaluated claims is a  
13 violation of the two times rule in the  
14 originating CAPC.

15 Our proposed and final list of  
16 complexity adjustments, as well as all the  
17 combinations that were evaluated, are provided  
18 in the Addendum J to our proposed and final  
19 rules.

20 In the calendar year 2026 OPPS ASC proposed  
21 rule, we are soliciting comments on potential  
22 refinements to our CAPC complexity adjustment

1 methodology.

2           Boston Scientific is recommending that  
3 CMS publish the current limited list of add-on  
4 codes for primary codes with status indicator J1  
5 that are eligible for complexity adjustment  
6 evaluation and publish the current methods to  
7 enable replication and confirmation of J1 plus  
8 add-on combinations.

9           Johnson & Johnson and AdvaMed are  
10 recommending that CMS update the complexity  
11 adjustment methodology to include the cost of  
12 all secondary J1 procedures when evaluating J1  
13 plus N procedure code combinations.

14           They have also requested that CMS  
15 provide additional detail on the final rule and  
16 claims accounting narrative so that stakeholders  
17 can easily replicate Addendum J in its entirety.

18           AdvaMed also recommends that CMS  
19 consider expanding its review of procedure  
20 combinations to include clusters of J1 and add-  
21 on codes and certain select HCPCS device codes,  
22 rather than only code pairs when cost and volume

1 criteria are met.

2 CMS continues to monitor the  
3 application and impact of the complexity  
4 adjustment criteria on CAPCs and may consider  
5 refinements to our CAPC complexity adjustment  
6 methodology in the future. This concludes my  
7 presentation.

8 DR. HAMBRICK: Thank you.

9 Boston Scientific, if you'd like to go  
10 ahead.

11 DR. HO: Hi. Thanks for your time and  
12 attention today. I'm Ta-Yuan, Director of  
13 Health Economics and Market Access for Boston  
14 Scientific, and I'm going to give an overview of  
15 the complexity adjustment methodology that CMS  
16 uses for J1 plus add-on code combinations and  
17 the unique challenges that add-on codes face.

18 Next slide, please. We believe that  
19 there are three key issues with the existing  
20 policy specific to add-on code combinations.  
21 First, CMS evaluates them separately and also  
22 uses a different method than they do for J1 plus

1 J1 code combinations.

2           The method is not clear enough about  
3 which add-on codes can be evaluated, and without  
4 more information about the method, we're not  
5 able to reconcile the cost statistics in  
6 Addendum J.           That really limits our ability  
7 to provide robust comment. We're requesting  
8 that CMS publish the list of add-on codes that  
9 can be evaluated and also provide details about  
10 the current methods so that we can make sure  
11 that the cost stats tie out.

12           Next slide, please. I'll use coronary  
13 FFR and IVUS as a background a little bit, and  
14 so we'll talk about this as established  
15 technologies that are used for the assessment  
16 and evaluation of coronary lesions, and their  
17 use is recommended by the clinical guidelines.  
18 In 2016, CMS added the FFR and IVUS initial  
19 vessel codes to the list of codes that can be  
20 evaluated.

21           Initially, it was just in combination  
22 with PCI, but the next year, when diagnosis



1 procedures were categorized as J1, those  
2 combinations also became eligible.

3 The following year, there was a request  
4 for CMS to add the FFR and IVUS for each  
5 additional vessel code to the list of codes that  
6 could be evaluated. CMS declined, stating that  
7 each additional vessel codes are add-ons to the  
8 initial vessel add-ons.

9 Next slide, please. J1 plus add-on  
10 code combinations are disadvantaged because the  
11 total number of claims that can be evaluated are  
12 fewer, and this leads to a reduced frequency and  
13 cost for each combination, making it harder to  
14 qualify.

15 For coronary FFR and IVUS, CPT guidance  
16 states that FFR and IVUS can be performed with  
17 the same diagnostic angiography and PCI codes,  
18 and so clinically, they could both be performed  
19 in the same episode of care and be billed on the  
20 same claim.

21 But CMS rules state that it will only  
22 evaluate claims with either of those codes on a

1 claim and not both. The table here shows  
2 combinations with the most common diagnostic  
3 intervention J1s, which are coronary angiography  
4 with left heart catheterization and coronary  
5 drug-eluting stent placement.

6 These combinations are mutually  
7 exclusive, and they don't include instances when  
8 FFR and IVUS might be used together in the same  
9 case. The volume and cost of those claims are  
10 excluded and don't appear in NMJ. Next slide,  
11 please.

12 When the policy was first created, CMS  
13 proactively published the list of add-on codes  
14 that are eligible for evaluation. But since  
15 then, CMS has maintained that list but not  
16 published it. Instead, they referred the public  
17 to NMJ for combinations that were evaluated.  
18 The number of add-on codes that are evaluated in  
19 NMJ has almost tripled in the past decade.

20 But when we look back to when CMS first  
21 published the list, the number of codes  
22 evaluated was less than the number of codes that

1       were eligible for evaluation. We don't know why  
2       some of the codes were evaluated and others  
3       weren't.

4               Coronary FFR and IVUS have been  
5       eligible and evaluated with diagnostic coronary  
6       angiography, and various combinations have  
7       qualified more than 75% of the time for the past  
8       decade.

9               However, they've never qualified with  
10      any PCI code until now. For 2026, CMS is  
11      proposing to qualify IVUS when used with  
12      coronary angioplasty. From a common standpoint,  
13      we're entirely reliant on the proposed data in  
14      NMJ, and it's a challenge because we can't  
15      confirm these data.

16              Next slide, please. We're unable to  
17      comment because we're unable to replicate the  
18      method and can't confirm the cost stats in NMJ.  
19      We also don't know how add-on codes interact  
20      with other add-on codes from an evaluation  
21      standpoint. Here's what we know.

22              For coronary FFR and IVUS, CMS

1 evaluates the initial vessel codes as mutually  
2 exclusive with diagnostic and interventional  
3 procedures, but they don't evaluate each  
4 additional vessel code. We're fortunate here  
5 that we have historical context from CMS, but --

6 MR. BAILEY: Pardon me. You have one  
7 minute remaining.

8 DR. HO: Thank you. Many other add-on  
9 codes don't have that benefit. What we don't  
10 know is how CMS would evaluate the case of add-  
11 ons to add-ons, such as multi-vessel FFR or  
12 IVUS, where both the initial vessel and each  
13 additional vessel code would appear on the same  
14 claim with the J1.

15 We also don't know what happens when a  
16 diagnostic procedure with FFR or IVUS converts  
17 to an interventional procedure. Let's go back  
18 to the previous example, which is the case of a  
19 coronary angiography and left heart cath with  
20 either FFR or IVUS.

21 This time, it converts to the coronary  
22 joint wound stem procedure. We believe that CMS

1 would ignore the FFR or IVUS add-on codes when  
2 angiography becomes secondary to the primary  
3 joint wound stem procedure, but we don't know  
4 for sure. Next slide, please.

5 In conclusion, we request that CMS  
6 publish the current list of add-on codes that  
7 are eligible for complexity adjustment and  
8 evaluation, and also publish the current methods  
9 to enable replication and confirmation of J1  
10 plus add-on code combinations. Thank you.

11 DR. HAMBRICK: Thank you. Are there  
12 any questions? Oh, questions for Dr. Ho. Is  
13 there anybody queued up, Ms. Davis?

14 MS. DAVIS: Currently, there are no  
15 raised hands.

16 DR. HAMBRICK: And in the chat, are  
17 there any questions?

18 MS. CESNIK: No questions in the chat.

19 DR. HAMBRICK: Thank you. I'd like to  
20 draw everybody's attention to a letter from  
21 Johnson & Johnson written by Chandra Branham.  
22 And they have some recommendations, which

1 include the complexity adjustment methodology.

2           Yeah, it's all about the complexity  
3 adjustment methodology. I'll give the panel a  
4 couple of minutes to read it, and then we will  
5 entertain any recommendations. But I'll give  
6 you a couple of minutes to read the letter from  
7 J&J Johnson & Johnson.

8           Okay. Are there any recommendations  
9 from the panel with respect to the comprehensive  
10 APC complexity adjustment?

11           MS. ARTIGUE: Hey, Dr. Hambrick, this  
12 is Jennifer Artigue. I'll make a recommendation  
13 again.

14           DR. HAMBRICK: Okay. Go ahead, Ms.  
15 Artigue.

16           MS. ARTIGUE: I recommend that CMS  
17 publish the list of add-on codes with status  
18 indicator J1 that are eligible for complexity  
19 adjustment evaluation.

20           DR. HAMBRICK: Is there a second?

21           DR. BEAN: Second.

22           DR. HAMBRICK: Discussion? All those

1 in favor, indicate by saying aye.

2 (Chorus of aye.)

3 DR. HAMBRICK: Opposed by nay. Any  
4 abstentions?

5 DR. MANAKER: I abstain.

6 DR. HAMBRICK: That was Dr. Manaker.

7 DR. MANAKER: Correct.

8 DR. HAMBRICK: Okay. Now is the time  
9 where you get to have one second -- no, a little  
10 minute or two to think back for the panel, think  
11 back about whether they want to make any more  
12 recommendations on any presentations that we've  
13 had today that maybe they thought about over  
14 lunch. I'll give you a few minutes so you can,  
15 you know, slip back to your book or your  
16 presentations or whatever.

17 MR. DIRKSEN: This is Blake Dirksen,  
18 not making a recommendation, just saying.

19 DR. HAMBRICK: Okay, all right. Well,  
20 thank you very much, Ms. Trevas. How long you  
21 want us to take a break?

22 MS. TREVAS: I believe 15 minutes at

1 the most.

2 DR. HAMBRICK: Okay, so why don't we  
3 set it to 2:30 or you want 2:35, just in case?

4 MS. TREVAS: Abby. Can Abby maybe  
5 weigh in on what she thinks is reasonable  
6 because she knows I will send this to you in  
7 about 15 minutes.

8 MS. CESNIK: I think as soon as you  
9 can, that's fine with me. I mean, we're running  
10 ahead of time, so please take as much time as  
11 you need, if you need a little more than that.  
12 I think 15 is good.

13 DR. HAMBRICK: Right. But we need to  
14 review them. So how about for the panel and the  
15 attendees, 2:45. We'll resume at 2:45.

16 MS. CESNIK: Okay, thank you.

17 DR. HAMBRICK: Thank you.

18 (Whereupon, the above-entitled matter  
19 went off the record at 2:14 p.m. and resumed at  
20 2:45 p.m.)

21 DR. HAMBRICK: Hello, the panel should  
22 be getting the recommendations, beginning with



1 the original recommendations. We have some  
2 questions about some of the information, which  
3 we'll go over as we go from page to page, and  
4 we'll call it out, and we'll have Ms. Trevas  
5 make any changes that we need to make at that  
6 time. So, panelists, let me know when you get  
7 it.

8 MR. DIRKSEN: I've received the email.

9 DR. HAMBRICK: Okay, let's open it up.  
10 And for the public and panel, we ask that you  
11 not take screenshots. These are preliminary and  
12 have not been finalized, so they're on the honor  
13 system here. Certainly, you may, obviously  
14 you're at the meeting, you can review them, but  
15 please don't take screenshots.

16 So the way we usually do this, we go  
17 from page-to-page and see if there's some  
18 changes. I know I have a question about one of  
19 the recommendations, and I think some other  
20 staff have a recommendation. There might need  
21 to be one edit, Ms. Trevas. So as we go through  
22 them, we'll call them out.

1                   So, does anyone have any questions  
2 about pages one and two? Panel members. Do  
3 they look all right to you?

4                   Let's go to page one to two. This is  
5 one where I had a question. Dr. Manaker, this  
6 is directed to you. I believe that when you  
7 were speaking, you talked about the hospital,  
8 too, I believe it was, presenting some evidence.

9                   And then depending on that evidence of  
10 miss billing, then you recommended, or would you  
11 like the recommendation to stand as it is  
12 currently on page -- I guess, well, it starts on  
13 one, but the recommendation is really on page  
14 two.

15                  DR. MANAKER: I'll take some advice  
16 from you, Edith, for Dr. Hambrick.

17                  DR. HAMBRICK: Either way, it doesn't  
18 matter. I thought it was part of your  
19 recommendation, and then others said they didn't  
20 think so. They thought it was -- it was just an  
21 introductory comment. So either way is fine.

22                  DR. MANAKER: Yeah, I meant it as a

1 comment, not to be part of the formal  
2 recommendation, but if it would help, because  
3 the folks in the hospital either don't show up,  
4 or they show up and the facts are different, I'm  
5 happy to put it into the recommendation.

6 DR. HAMBRICK: No, if you're satisfied,  
7 that's fine. No problem. Okay. So anything on  
8 page two? Okay. Moving on to number four,  
9 anything there, any panel member wants to  
10 change? We're going to page five, I mean number  
11 five, line 46. Number six, line 50. Number  
12 seven. Number eight.

13 Mr. Rice, I think you had a comment on  
14 line 63?

15 MR. RICE: Yeah, 63, just the  
16 beginning. It says the panel recommends that  
17 CMS. It says that twice.

18 DR. HAMBRICK: Ah, yes. Okay, Ms.  
19 Trevas will take care of that. And number nine.  
20 Number 10. Number 11, page four to five. And  
21 then on line 93, I think there was a potential  
22 reframing or something that might need to happen

1 with this one. Was there further elucidation  
2 that needed to happen with number 12, Mr. Rice?

3 MR. RICE: Yeah, I think this one just  
4 -- it says post a list of add-on codes with the  
5 status indicator J1. Yeah, the add-on code  
6 wouldn't have a status indicator J1, so I think  
7 that's a little confusing.

8 MS. ARTIGUE: Yes, I'm sorry, Mr.  
9 Rice, it should be that CMS published a list of  
10 add-on codes for prime codes with the status  
11 indicator J1.

12 MR. RICE: Okay.

13 MS. ARTIGUE: So, if it's an add-on to  
14 a J1 primary code.

15 MR. RICE: Okay, yeah, that makes sense  
16 to me.

17 MS. ARTIGUE: Okay, sorry about that.

18 DR. HAMBRICK: Okay, all those -- is  
19 there a second to an amendment to the  
20 recommendation?

21 MS. SMITH-LLOYD: I'll second.

22 DR. HAMBRICK: Discussion from the

1 panel? All those in favor of the amended  
2 recommendation indicate by saying aye.

3 (Chorus of aye.)

4 DR. HAMBRICK: Opposed nay. Any  
5 abstentions? Okay.

6 MR. RICE: Sorry, just say publish the  
7 list of add-on codes for primary codes with a  
8 status indicator J1. Sorry to interrupt the  
9 voting process.

10 DR. HAMBRICK: Okay, did you get that,  
11 Ms. Trevas?

12 MS. TREVAS: Yes, I have it. Would you  
13 like me to read it?

14 DR. HAMBRICK: Or would you prefer to  
15 see it, panel? That way, you'll know once it's  
16 displayed? Or is that not possible?

17 DR. MANAKER: It is displayed, Edith.

18 MS. ARTIGUE: Yeah, we can see it. It  
19 looks good. It looks good. Thank you. Thanks,  
20 Dana.

21 MS. CESNIK: Edith, this is Abby. I'm  
22 displaying it right now. Just let me know if

1       you need me to --

2               DR. HAMBRICK: Great.

3               MS. MARCOS: Abby, was it primary or  
4       was it prime?

5               MS. CESNIK: The presentation was  
6       prime.

7               DR. MANAKER: It was technically  
8       correct within your system. Prime or primary?

9               MR. RICE: We usually refer to them as  
10      primary.

11              MS. ARTIGUE: Yeah, it's like coders  
12      would refer to it as well.

13              DR. MANAKER: Yeah. And, Edith, we can  
14      consider these as editorial and not have to have  
15      another vote.

16              DR. HAMBRICK: Yes, I agree with that.  
17      Prime to primary, I agree with that. Sorry, I  
18      was looking at the document, not at the screen.

19              MS. CESNIK: I just wanted to confirm  
20      that what's displayed is how we'd like it  
21      corrected.

22              MS. ARTIGUE: Yes, Abby, thank you.

1 DR. HAMBRICK: Okay. Moving on to the  
2 next one, APC groups. Any changes there? Okay.  
3 And I think that's the end, isn't it, Abby?  
4 Nope, scroll on down. Something is down there.  
5 Okay. All right. Very good.

6 Okay. Well, I'm so glad we had this  
7 time together, but thank you all who  
8 participated, especially our great panelists and  
9 the Division of Outpatient staff, including our  
10 DFO, Abby Cesnik, the transcriptionist, and her  
11 team, Dana Trevas, Joanna Case, and Jasper  
12 Wittig. And Marvelyn Davis, who was our  
13 moderator today. Thank you, thank you, thank  
14 you.

15 Everybody have a great week, and  
16 getting into the Labor Day holiday. If you  
17 actually get a holiday on Labor Day, since you  
18 all are clinical, a lot of you, you might not  
19 have a Labor Day holiday. But thanks, everybody.  
20 Take care. We'll see you next year. Good job.

21 (Whereupon, the above-entitled matter  
22 went off the record at 2:55 p.m.)

## 1       C E R T I F I C A T E

2       This is to certify that the foregoing transcript  
3       was duly recorded and accurately transcribed  
4       under my direction; further, that said  
5       transcript is a true and accurate record of the  
6       proceedings; and that I am neither counsel for,  
7       related to, nor employed by any of the parties  
8       to this action in which this matter was taken;  
9       and further that I am not a relative nor an  
10      employee of any of the parties nor counsel  
11      employed by the parties, and I am not  
12      financially or otherwise interested in the  
13      outcome of the action.

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20      Court Reporter  
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22