August 29, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-1772-P
7500 Security Blvd.
P.O. Box 8010
Baltimore, MD 21244-1810

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating (CMS-1772-P)

Dear Administrator Brooks-LaSure:

TriSalus Life Sciences® (TriSalus) welcomes the opportunity to comment on the calendar year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System proposed rule entitled "*Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating*" (proposed rule).

TriSalus is a company focused on transforming cancer care – specifically, how liver and pancreatic tumors are treated through our immunotherapy platform, which is focused on overcoming the two primary barriers that limit treatment success for liver and pancreatic tumors and enable more patients to benefit from improved drug delivery to the disease site. A key component of our platform is an on-market FDA-cleared device, the TriNav Infusion System (TriNav®), which creates new opportunities for clinical success in historically challenging diagnoses by transforming how therapeutics are delivered to liver and pancreas tumors using interventional radiology intravascular approaches. TriNav uses Pressure-Enabled Drug Delivery™ (PEDD™) technology, which is a method of therapeutic administration that modulates pressure and flow within blood vessels to improve therapy uptake and tumor

response. Today, PEDD™ devices are being used with standard of care (SoC) chemotherapy and radiation therapy (Y90) bead products for patients with primary and metastatic liver tumors. With these SoC therapies, existing and emerging data indicate that PEDD™ improves drug delivery and response rates.

Published studies looking at transarterial chemoembolization (TACE) and transarterial radioembolization (TARE) demonstrate higher particle delivery with PEDD™ in tumors and less delivery to normal liver tissue.[1, 2] Higher particle distribution in the tumor is correlated with improved disease response, which in turn has been correlated with improved survival. Less particle in background liver tissues reduces potential for liver toxicity. Based on these clinical data, TriSalus received approval from the Centers for Medicare & Medicaid Services (CMS) for Transitional Pass-Through (TPT) status for TriNav beginning on January 1, 2020 and this provided the opportunity for Medicare patients to benefit from this innovative and impactful technology. TriNav currently is billed for under HCPCS code C1982 and paired with the primary service CPT codes, 37242 (used for mapping) and 37243 (used for the procedure).

In addition to our focus on improving current SoC, TriSalus is committed to developing cutting-edge therapies for those diagnosed with liver cancer through enabling more patients in need to benefit from the advances in immunotherapy. Our platform integrates TriNav with SD-101, a toll-like receptor 9 agonist in combination with checkpoint inhibitor therapy to improve patient response rates. TriSalus is studying the ability of SD-101 to reactivate the immune system within liver and pancreas tumors, which we hope will enable more durable responses to other immunotherapeutics and further improve patient outcomes. TriSalus is working in partnership with some of the country's leading cancer centers to rapidly bring this potentially transformative treatment approach to patients living with liver and pancreatic tumors.

Liver cancer is a global health care challenge. Unfortunately, treatment success is limited with a poor prognosis and limited responsiveness to systemic therapy. Locoregional therapies play an important role in patients at all stages. Transcatheter arterial therapies, where TriNav is used, can serve as an adjunct or alternative to surgical intervention or thermal ablation and can provide a means of local disease control in patients with intermediate and advanced disease and is a preferred treatment according to key guidelines.[3]

Medicare claims data show that the cost of TriNav is not currently reflected in Medicare payment. As such, if TPT status expires this year without a workable solution to address the data distortions, reimbursement for the above procedures will be insufficient to cover the cost of the procedure when performed with TriNav. This could lead to less effective treatment and increased toxicity, as hospitals would face financial pressure to use an inexpensive conventional microcatheter for these procedures, which are significantly less costly. Hospitals and clinicians should prioritize patient outcomes and not change treatment direction due to financial pressures. However, significant underpayment for the use of TriNav will make the adoption of improved treatments infeasible as providers will not consistently operate at a loss.

Further, it is imperative that the agency consider how reduced access to improvements to the SoC will impact people of color and exacerbate health inequities. All liver cancer patients will benefit from improved therapy uptake to increase tumor response. However, hepatocellular carcinoma (HCC), the primary form of liver cancer, disproportionately affects disadvantaged populations and they especially will be impacted by lack of access to PEDD™. Specifically, Black patients with HCC are vulnerable due to limited access to, and wait times for, other forms of treatment, such as liver transplantation and surgery.[4] Black patients who develop HCC are more likely to have larger tumors, more advanced disease stage, and more aggressive disease overall.[5] After diagnosis, Black patients with HCC are more likely to have worse overall survival, and patients with low incomes who are underinsured or uninsured face similar disadvantages.[6] The optimization of therapeutic delivery is important for all, but this is especially important for patients with more advanced HCC and when access to other treatments may be limited. Appropriate reimbursement for PEDD™ devices is needed to ensure equitable access to a drug delivery technology that has been shown in multiple clinical reports to improve therapeutic delivery and response rates, while decreasing normal liver tissue exposure.

In general, our comments focus on the agency's proposal not to extend TPT status payments by providing additional quarters of separate payment for any device category whose TPT payment status will expire between December 31, 2022 and September 30, 2023. TriNav's TPT status is set to expire on December 31, 2022 and is one of the devices that would be adversely impacted by the agency's proposal.

For 2022, CMS used its equitable adjustment authority under section 1882(t)(2)(E) of the Social Security Act and provided up to four quarters of separate payment for drugs, biologicals and a device whose TPT status expired between December 31, 2021 and September 30, 2022. The agency used 2019 claims data instead of 2020 claims data to set 2022 payment rates because of concerns of the impact of the COVID-19 pandemic on 2020 claims data. CMS therefore provided this separate payment in order to "mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs."[7]

TriSalus urges CMS not to finalize this proposal and instead extend TPT payment status for TriNav by providing four additional quarters of separate payment in 2023. The circumstances that warranted last year's TPT extension, including the severe impact of the COVID-19 pandemic, still persisted well into 2021 and continue to adversely impact the adoption of TriNav today. We are concerned that absent an extension of TPT, CMS will not have adequate data that can accurately reflect estimates of the costs associated with furnishing services when using TriNav for 2023. Therefore, TPT status for this device should be extended for another year so that additional cost information can be collected to provide the best available data required for rate setting purposes.

In addition, we ask CMS to conduct an assessment of CPT code 37243 when TriNav is used for purposes of APC assignment. Currently, these codes are assigned to APC 5193, Level 3 Endovascular procedures. However, the resource costs associated with the use of TriNav

should make the underlying code eligible for a complexity adjustment to APC 5194, Level 4 Endovascular procedures. We believe this alternative mechanism would ensure that patients have continued access to this important technology. While we recognize that CMS may not have sufficient time prior to the release of the final rule to make this payment policy change, should CMS not extend TPT payment status or payment adjustment to the underlying code, we ask that CMS instead provide separate payment equivalent to the TPT payment for 2023, while the complexity adjustment assessment is performed.

Our comments address the following areas in support of our requests that CMS (1) either extend TPT status for TriNav or provide a separate payment method to reflect the costs of TriNav if not through TPT status extension, and (2) establish a complexity adjustment for CPT code 37243 when TriNav is used, reassigning this code from APC 5193 to 5194 in such instances:

- Background on TriNav
- Impact of the COVID-19 pandemic on the adoption of TriNav
- Impact of using 2021 claims data for setting 2023 rates for TriNav
- An additional year of TPT for TriNav is needed to ensure adequate data is provided for CMS to develop appropriate rate setting
- Rationale for a complexity adjustment for TriNav

I. Background on TriNav

TriNav is a 0.021-inch lumen microcatheter with a SmartValve® self-expanding tip. SmartValve® supports pressure generation, which enables substantial improvement in the delivery of therapeutic agents to selected sites in the peripheral vascular system, as determined by CMS under Medicare requirements.[8] As a result, TriNav was granted TPT status in January 2020 based on clinical evidence demonstrating improved therapeutic delivery and the highly differentiating, innovative nature of TriNav technology.[9]

TriNav's initial TPT designation was based upon strong clinical evidence that its delivery technology enhances therapeutic uptake in high-pressure liver tumors through a mechanism of action not available in any other device. Better therapeutic uptake predicts improved response to treatment and superior clinical outcomes, which would be expected to drive full utilization of this novel delivery technology under normal circumstances.

A significant barrier to therapeutic delivery is high intratumoral pressure (ITP), which can compress vessels and reduce or halt blood flow to many parts of the tumor.[10, 11] In this environment, the ability of conventional microcatheters to deliver therapeutics to the intended target can be severely limited. The TriNav system has been designed to overcome ITP with its SmartValve® technology. SmartValve works in sync with the cardiac cycle to physiologically and atraumatically increase local vascular pressure at the target location close to the tumor, in addition to driving blood flow into tumor-feeding vessels.

TriNav has been shown to increase the deposition of therapeutics to the tumor in both chemoembolization (TACE) and radioembolization (TARE) procedures while decreasing off-target deposition, both important goals for these treatments. Consistent with CMS guidance,[12] providers are instructed to bill for the use of TriNav (C1982) when performing CPT codes 37242 and 37243. Both codes are currently assigned to APC 5193. Ensuring access to TriNav for liver cancer patients undergoing these procedures is a critical success factor. Indeed, therapeutic success may not have been possible in some cases without TriNav.

Preclinical and clinical studies support the superior benefit of hepatic arterial infusion using TriNav as compared to conventional microcatheters. Several published clinical studies demonstrate that, when using TriNav, physicians achieve more significant tumor deposition of therapeutics in both TACE and TARE procedures and in delivering chimeric antigen receptor (CAR) T-cells to the liver. TriNav delivery improvements include:

- Increasing TACE delivery by 60% and pathologic response to TACE from 34% to 89%[1]
- Increasing Radionuclide deposition for TARE procedures by 33-90%[2] and Y90 therapeutic delivery by 23%[13]
- Increasing CAR T-cell delivery by 500%[14]
- Improved precision of TACE and TARE delivery through a reduction in exposure of non-tumor tissue to potentially toxic agents[2, 13]

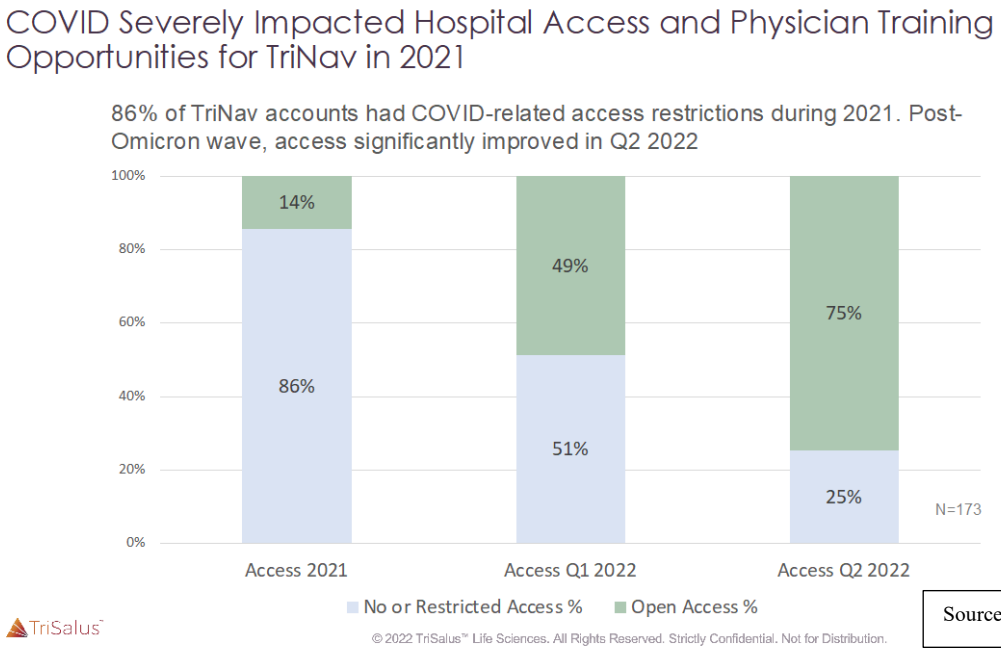
Beyond our desire for appropriate adoption of our delivery technology to enhance patient outcomes with the current SoC of TACE and TARE procedures for liver tumors, TriSalus is deeply committed to combining this novel technology with its development of immunotherapy treatments for liver and pancreatic tumors. Immunotherapy has revolutionized cancer care for many tumor types, but liver and pancreatic cancer patients have not benefitted due in part to delivery barriers like ITP. An extension of TPT status for TriNav is needed to advance care further and address the significant unmet medical needs of patients with solid tumors. If the costs associated with TriNav are not reflected in reimbursement, patients will not have sufficient access to future innovations.

II. Impact of COVID on TriNav Utilization

Due to its unique mechanism, the TriNav device **must be introduced directly to physicians**. TriSalus representatives must train the physician in the initial procedures in person to assure safe and effective utilization and appropriate case selection.

Due to the COVID-19 pandemic, physician access was severely limited overall, and at some sites, access was suspended entirely in 2020 and parts of 2021. Even though restrictions were relaxed somewhat during the summer months of 2020, many of the restrictions were reimplemented at the end of 2020 and into 2021, when a resurgence of the Omicron strain of COVID-19 began spreading across the United States. TriSalus' ability to provide the education

and training necessary to utilize the TriNav technology to oncologists, interventional radiologists, and other hospital staff was once again significantly limited.



Source: Internal TriSalus Data, Data on File

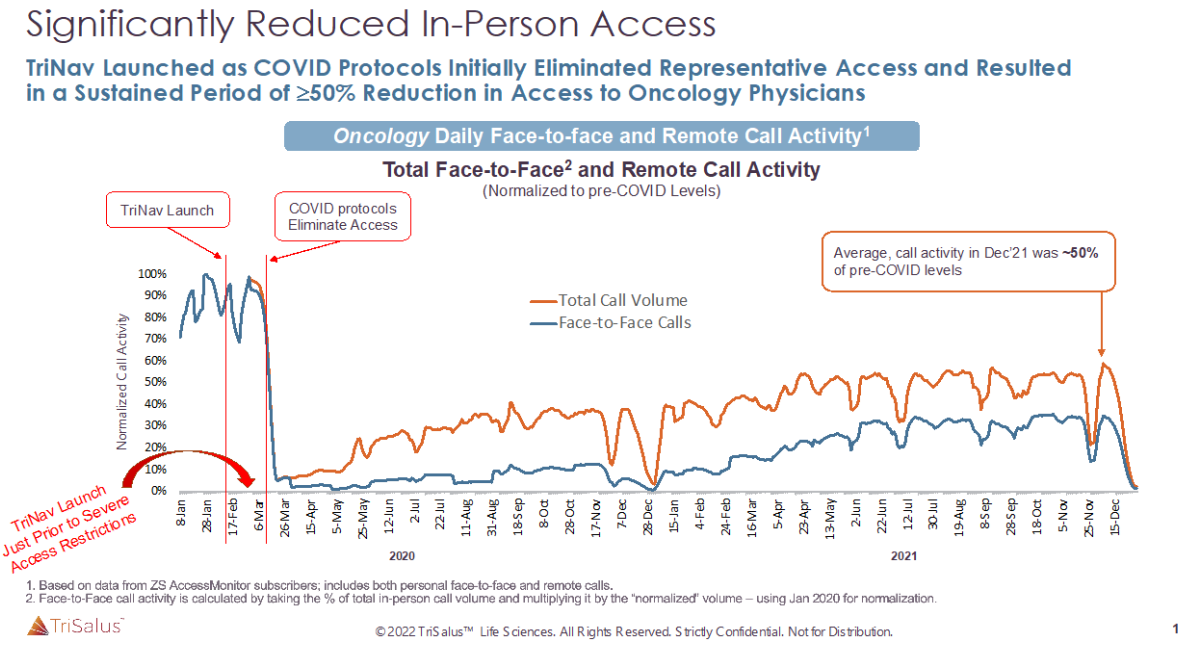
As a direct consequence, TriNav uptake was heavily impacted throughout 2020, and this negative impact continued into 2021. Pandemic COVID restrictions reduced TriSalus representative access to oncology physicians, interventional radiologists, and hospitals by over 75% on average, resulting in severely depressed adoption during TriNav's critical launch years. **The reduced access disproportionately harmed TriNav uptake relative to devices that do not require on-site support, as COVID-related hospital entry restrictions severely limited our ability to educate and train physicians on the use of our technology**. For those limited instances where providers adopted TriNav, we have learned of difficulties they experienced navigating the TPT status payment pathway due to potentially confusing coverage and coding guidance related to the use of TriNav. For example, CMS released two separate MLN articles providing guidance on appropriate billing of C1982. In one,[15] CMS states TriNav may be billed with CPT code 37242, and in another,[16] CMS states C1982 must always be billed with CPT code 37243.

We have heard directly from several large health systems that the use of TriNav was not sufficiently documented when performing TACE and TARE procedures. Further, our efforts to obtain direct guidance from CMS on appropriate billing has been unsuccessful, meaning the cost of TriNav is not likely captured in all of the instances it has been used. Finally, we are coordinating with provider groups such as the Society of Interventional Radiology regarding the use of TriNav and appropriate billing to reflect the associated costs, but it is clear that the COVID-19 pandemic not only impacted adoption, but also appropriate cost capture during 2020 and 2021.

These data also demonstrate that COVID's impact persisted well into 2021, meaning any TriNav data collected and assessed during this time period would not be reflective of the experience of other TPT awardees or if TriNav launched at any time other than when it did.

TriSalus created a rigorous sales forecast based on industry benchmarks and literature and validated its forecast with ZS Associates, an industry-leading consultant. This forecast, built in 2019, could not anticipate the devastating impact that the COVID-19 pandemic would have on normal hospital function and representative access to hospitals and physicians in 2020. We note that TriSalus took steps to increase the adoption of TriNav when it was safe and appropriate, but efforts continued to stall in the face of new COVID variants in 2021.

Multiple factors influence launch trajectories, the most important being access to the clinicians who will trial and adopt the product. TriSalus launched TriNav in February 2020, a year marked by the start of 12 months of virtually no in-person access. TriSalus pivoted to engage physicians via forms of virtual education (e.g., tele-detailing). Still, that approach resulted in access levels significantly reduced from pre-COVID levels due to the drastic operational changes necessitated by the pandemic. Even where TriSalus could connect with physicians remotely, the in-person interaction required for training physicians on the proper use of the device was simply not possible. This unprecedented lack of access in 2020, continuing through 2021, severely impacted our launch trajectory, and as a result, TriNav use and uptake are significantly depressed. In fact, in the first quarter of 2022, we have seen a continued and significant reduction in access to physicians relative to pre-COVID levels.



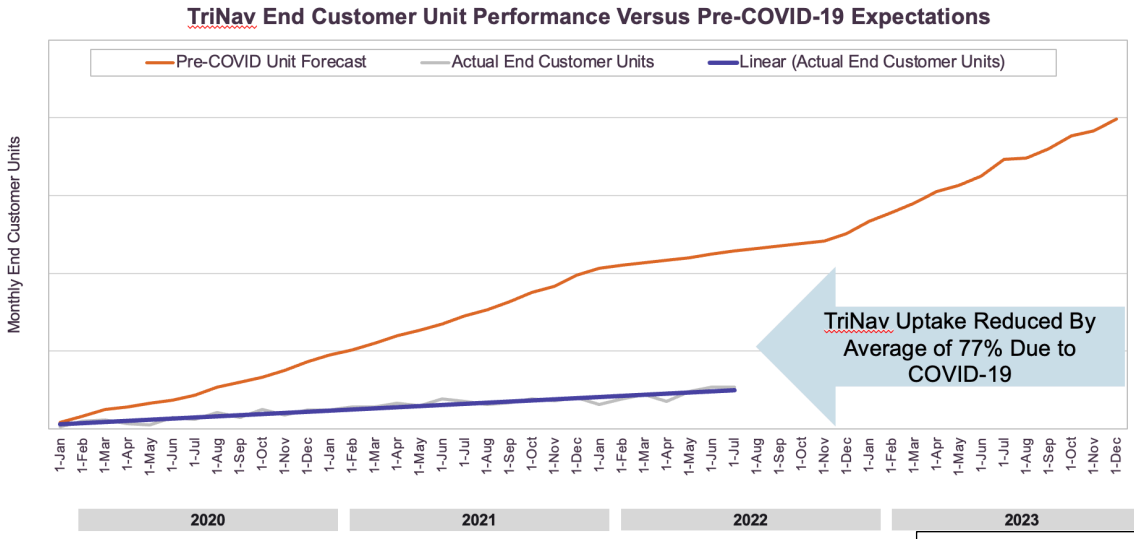
Source: ZS Associates

TriSalus launched TriNav at the start of the COVID-19 pandemic, and, as verified by ZS Associates, within a month of launch, access to physicians and provider facilities fell to less than 10% of pre-pandemic levels. In the face of these challenges, it is not surprising that the launch of the innovative TriNav device did not achieve its expected uptake.

Sales performance for 2020 and 2021 clearly shows an unusually flat uptake curve for an innovative device with clinical data to support its benefit to patients versus SoC. We note, however, that when considering the minimal sales volume, the documented use of TriNav is misaligned. Although TriNav is not used exclusively for Medicare beneficiaries, the disparity in claims with C1982 and our sales volume point to significant under-reporting of TriNav utilization in 2020 and 2021.

Covid-attributable Reduction in Uptake and Patient Access

The Opportunity for TriNav to Benefit Patients Has Been Significantly Impacted By COVID-19 and Hospital Access Challenges



Source: Internal TriSalus Data, Data on File

III. Impact of using 2021 claims data for setting 2023 rates for TriNav

Using 2021 outpatient claims for 2023 rate setting will significantly impact the utilization of TriNav, as these data do not reflect an accurate accounting of related costs. In the proposed rule, CMS proposed to return to the regular process of utilizing claims data from two years prior to the year for which it is setting rates, specifically CY 2021 outpatient claims for CY 2023 rate setting. As we have learned and as described above, we do not believe CY 2021 outpatient claims data would be appropriate for ratesetting purposes. Inaccurate rates for procedures performed when using TriNav will result in hospitals limiting utilization.

As a result, we are concerned that hospitals will utilize less costly conventional microcatheters in place of TriNav, depriving patients of a technology that can significantly improve the therapeutic concentration of either the chemotherapy or radiological beads in the tumor and limit exposure to healthy tissue.[1, 2, 13] Numerous studies have shown that the conventional microcatheter is inferior relative to PEDD™ in delivering therapeutics to the disease site and in avoiding safety issues due to less selective delivery to non-tumor tissue. We ask CMS to reconsider this position especially as it relates to TriNav's TPT status.

IV. An additional year of TPT status for TriNav is needed to ensure adequate data is provided for CMS to develop appropriate rate setting

TriSalus was uniquely affected versus other TPT awardees due to our need to be **in person** to educate and train physicians to ensure appropriate adoption of our technology and given the coding and billing issues that have been described by those who have utilized TriNav. TriSalus was significantly impacted initially at its time of launch in early 2020 through mid-2021 because of the COVID-19 pandemic. Essentially, we lost 1.5 years of the TPT period, which will significantly impact the data available to CMS for TriNav rate setting purposes. An additional year will be necessary to demonstrate the full value of the technology with current SoC therapies, provide CMS with the appropriate information needed to ensure that the reimbursement rates accurately reflect the cost of using TriNav so that patients have access to this important drug delivery technology, and ensure that TriNav can enable the next generation of immunotherapies for patients in need.

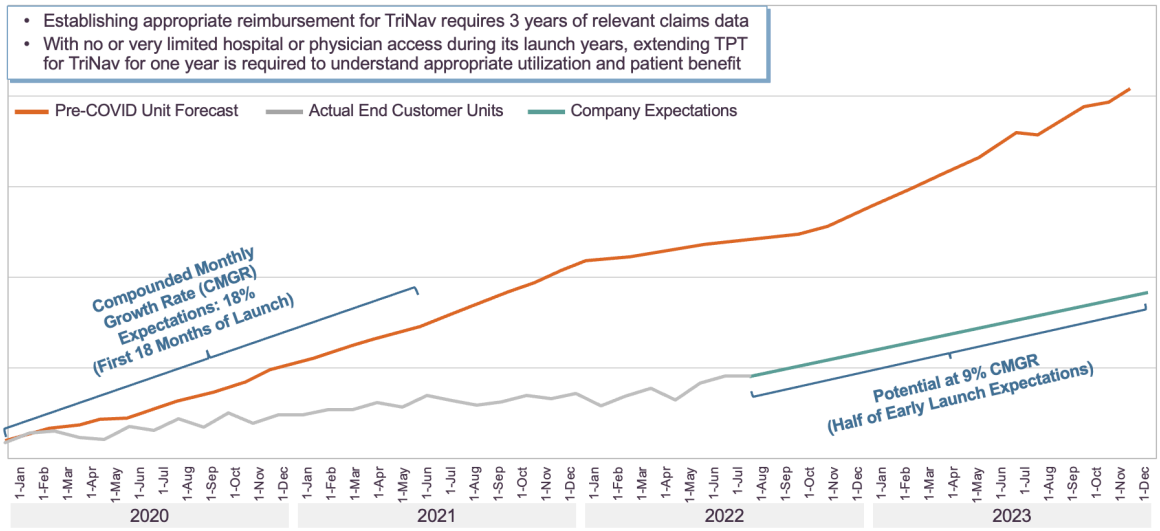
Each year of TPT authorization is critical for data collection, with successive years building on prior years. Without an additional year to generate adequate claims data for rate setting purposes, we are effectively limited to less than two years of meaningful claims data, which would be inconsistent with the TPT statutory and regulatory framework. We fear that terminating TPT status for TriNav at the end of 2022 will significantly undermine patient access to this innovative and highly effective liver cancer treatment as the costs will not be accurately captured moving forward. In particular, we are concerned that this will exacerbate healthcare disparities for underserved patient populations who may not be located in the limited areas where TriNav has been adopted.

As illustrated below, the adoption of TriNav has stagnated well into 2021 compared against our pre-COVID forecast. As described above, we strongly believe that the reduced uptake is a direct factor of COVID-19, meaning TriNav experienced more than a year of significant, COVID-19-attributable barriers. In other words, we do not believe basing TriNav Medicare reimbursement rates on either 2020 or 2021 claims data would be appropriate. As we approach Q4 of 2022, it appears we are reaching a turning point, meaning a one-year extension of TPT should be sufficient to ensure appropriate claims data are considered in ratesetting for 2024.

Additional Time is Needed to Overcome COVID Impact

A One-year TPT Extension Provides CMS with the Opportunity to Establish Appropriate TriNav Utilization and Patient Benefit

TriNav End Customer Unit Performance vs. Pre-COVID-19 Expectations



Source: Internal TriSalus Data, Data on File

As CMS previously granted TPT extensions to those devices, drugs, and biologicals with expiring TPT status between December 31, 2021 and September 30, 2022, we ask that you again provide an extension for TriNav. We believe this would be consistent with the intent of the TPT program as established by Congress and within CMS's equitable adjustment authority under section 1833(t)(2)(E) of the Social Security Act.

In the CY 2022 OPPS final rule, CMS described the necessity of this equitable adjustment "to ensure that [CMS has] full claims data from CY 2021 with which to set payment rates beginning in CY 2023." Further, CMS stated that "it is necessary to pay separately for these products in CY 2022 in a manner that mimics continued pass-through status, rather than having to set rates and make APC assignments and packaging decisions for these products for CY 2022 based on data from CY 2020, which [CMS does] not believe is the best available data for this purpose."[7]

In the CY 2021 OPPS proposed rule, CMS described the rationale for this proposal in greater detail, stating:

> [D]ue to the effects of the COVID–19 PHE, we are proposing to generally use CY 2019 claims data instead of CY 2020 claims data in establishing the CY 2022 OPPS rates and to use cost report data from the same set of cost reports originally used in CY 2021 final rule OPPS rate setting. <u>If our proposal to use CY 2019 data, rather than CY 2020 data, to inform CY 2022 rate setting is finalized, we would effectively remove approximately one year of pass-through data collection time for rate setting purposes</u>. (Emphasis added).[17]

Based on the above, the rationale set forth in the preamble of the CY 2022 OPPS proposed rule for extending pass-through status for medical devices whose TPT status ended on December 31, 2021, is to compensate for not using CY 2020 data when setting CY 2022 payment rates. TriSalus agrees with CMS's rationale and final policy for CY 2022.

We believe this rationale is equally applicable to the CY 2023 rate setting policy. These circumstances that the agency described last year apply to TriNav, which was granted TPT status in January 2020, and these data should be removed from consideration due to the unprecedented situation resulting from the COVID-19 pandemic. As described above, the impact of COVID persisted into 2021, and we do not believe CY 2021 claims data should be used in CY 2023 rate setting. Subsequently, we believe CMS is justified in again using its equitable adjustment authority to provide an additional four quarters of separate payment for TriNav to ensure sufficient data in CY 2024 rate setting.

Assuming CMS finalizes its proposal to use CY 2021 data for CY 2023 rate setting in general, extension of TPT status for TriNav is nonetheless justified and necessary. The TPT framework is meant to gather data separately from the underlying payment system. Effectively, TPT fulfills its purpose by establishing a set of data to compare to overall costs and utilization. The best available data for overall OPPS ratesetting may not be the best available data to reflect the ***relative*** cost and utilization of new technologies; technologies that, by CMS's own exacting standards, are so different and improved relative to other technologies that they qualified for TPT status. Indeed, CMS proposes to use cost report data from prior to the pandemic because it believes that it is the best approximation of expected costs, despite dataset incongruity. Similarly, we urge CMS to use the best available data for TPT status—and we strongly believe that cannot be data from CYs 2020 or 2021.

The primary purpose of the TPT period is to allow CMS to collect data on the cost of new technology derived from Medicare claims for new devices, drugs, and biologics that represent a substantial clinical improvement over existing technology. If CMS does not utilize the accurate claims data from the three years in which a device has TPT status for determining appropriate pricing, the purpose of TPT status is not met. If CY 2020 or CY 2021 data are used for TriNav, the resulting rates for CY 2023 will be inaccurate and effectively eliminate at least one year of TPT data.

V. If TPT status is not extended for TriNav in 2023, we recommend CMS to apply a complexity adjustment to CPT code 37243 when paired with C1982 and move the CPT code 37243 from APC 5193, Level 3 Endovascular procedures, to APC 5194, Level 4 Endovascular procedures

TriSalus recommendation

- If CMS does not extend TPT status for TriNav for an additional four quarters in 2023, in order to ensure Medicare patients have continued access to this important technology, CMS should apply a complexity adjustment to CPT code 37243 when paired with C1982

and move CPT code 37243 from APC 5193, Level 3 Endovascular procedures, to APC 5194, Level 4 Endovascular procedures.

- This is supported by TriNav meeting the criteria for a complexity adjustment and allow for this important technology to be available to Medicare recipients.

In the CY 2023 OPPS proposed rule, it is unclear how CMS is proposing to provide reimbursement for the utilization of TriNav. Without clarification, we assume that CMS will continue to assign the use of TriNav to CPT code 37243 and provide reimbursement under APC 5193, Level 3 Endovascular procedures.

Based on an analysis of Medicare claims data, payment under current Medicare payment policy would be inadequate to cover the cost of TriNav. Below is an example of the payment shortfall a hospital would experience *per procedure* if TriNav is to be reimbursed under APC 5193.

			Without C1982	**With C1982**	
HCPCS	**APC**	**Payment Rate**	**Geometric Mean Cost (GMC)**	**GMC**	**Payment rate as % of GMC**
37243	5193	$10,760.97	$11,976.03	$ 25,253.03	42.6

Based on feedback from clinicians and hospitals, it is likely that in this scenario hospitals will severely restrict or even eliminate TriNav access since they could not sustain the financial losses due to the inadequate payment rate. Based on analysis from the Moran Company (TMC), the current payment rate for CPT code 37243 under APC 5193 is approximately 42.6% of the geometric mean cost (GMC) for this service when used in conjunction with TriNav (C1982). We are concerned that the significant gap between true costs and proposed payment for procedures billed under CPT code 37243 and including TriNav, would result in significant barriers to patient access to an important and innovative treatment approach that can improve therapeutic delivery versus the current SoC.[1, 13]

Furthermore, CMS would be incentivizing the use of an inferior, conventional technology that can neither claim improved perfusion to the tumor and higher concentration of therapeutic delivered to the tumor tissue while avoiding healthy tissue, nor claim improved tumor response rates.[1]

If CMS does not extend TPT status for TriNav for an additional four quarters in 2023, in order to ensure Medicare patients have continued access to this important technology, CMS should apply a complexity adjustment to CPT code 37243 when paired with C1982 and move CPT code 37243 from APC 5193, Level 3 Endovascular procedures, to APC 5194, Level 4 Endovascular procedures.

CMS has made similar payment policy changes in the past when the use of technology during a procedure resulted in atypical costs associated with a primary procedure. We therefore ask

CMS to assess whether CPT code 37243 would be eligible for a complexity adjustment when TriNav (HCPCS code C1982) is used.

In the CY 2018 OPPS proposed and final rule,[18] CMS established C9738 to allow for a complexity adjustment to APC 5373 (Level 3 Urology and Related Services). According to CMS, blue light cystoscopy (Cysview) was granted TPT status and assigned code C9275. Following Cysview's TPT status expiration in 2012, CMS implemented new code C9738 to account for the costs for blue light therapy. As CMS stated in the CY 2018 rulemaking cycle, blue light cystoscopy represents an additional elective but distinguishable service as compared to white light cystoscopy, requiring additional equipment among other resources. Furthermore, the performance of blue light cystoscopy greatly improved outcomes for beneficiaries beyond traditional white light cystoscopy.

The current situation for TriNav is analogous to that of Cysview – the use of TriNav is an additional elective but distinguishable service that involves significant additional equipment costs. As described above, drug delivery and clinical outcomes from using TriNav are superior to the use of conventional microcatheters when performing these procedures. Further, existing CPT code descriptors do not recognize the use of TriNav in the performance of either CPT code 37242 or 37243, but existing claims data illustrate that the use of TriNav is a distinct element of CPT code 37243, used after a conventional microcatheter is used in the performance of CPT code 37242. In other words, not only is a conventional microcatheter used, but TriNav is also used to improve efficacy of the procedure. Furthermore, the use of TriNav greatly improves beneficiary response to treatment and is a significant additional cost not otherwise captured.

Recently, we asked TMC to analyze Medicare claims data and evaluate whether TriNav, identified by HCPCS code C1982, would qualify for a complexity adjustment when it is billed with HCPCS codes 37242 and 37243. To perform this work, TMC analyzed the 2021 OPPS data that are used to set rates for 2023. Ultimately, TMC found that when paired with HCPCS code C1982, HCPCS code 37243 is eligible for a complexity adjustment. We would be happy to share the more detailed analysis and calculations should those be helpful to CMS.

Key Findings

- There are 158 claims of HCPCS code 37243 billed with C1982. There are fewer than 11 claims with HCPCS code 37242 billed with C1982.
- HCPCS code 37243 claims billed with C1982 would meet the volume threshold for complexity adjustment using CMS's comprehensive methodology. These claims would likely also meet the cost criterion and would be adjusted from APC 5193 (Level 3 Endovascular procedures) to APC 5194 (Level 4 Endovascular procedures).
- If CMS makes a complexity adjustment for 37243 claims with C1982 then the payment to cost ratio for these claims will be 0.7. If CMS does not make this complexity adjustment, the payment to cost ratio will be 0.4.

As described further below, the use of TriNav in conjunction with 37243 meets the two primary complexity adjustment requirements as there are more than 25 claims (frequency criterion) and exceeds the cost threshold for the complexity adjustment (cost criterion).

			TMC Comprehensive Replication		Cost	Complexity Evaluation	
HCPCS	APC	Complexity Adjusted APC	Total Claim Count used in Rate Setting	Geometric mean cost	Threshold for Complexity Adjustment	Cost Criteria Met	Volume Criteria Met
37242+ C1982	5193	5194	*	$ 27,800.81	$ 15,962.16	Yes	No
37243+ C1982	5193	5194	158	$ 25,253.03	$ 15,962.16	Yes	Yes

*Per our CMS data-use agreements, cells with counts less than 11 are blinded.

HCPCS code 37242 billed with C1982 meets the cost criterion for a complexity adjustment; however, HCPCS code 37242 billed with C1982 would not meet the volume threshold because frequency of claims is not 25 or greater.

HCPCS code 37242 is intraprocedural mapping and imaging guiding procedure ("mapping procedure") necessary to complete the procedural intervention. TriSalus received confirmation from CMS in early 2021 that this code was also eligible for TPT payment when TriNav is used. Due to the late notification, and lack of public disclosure by CMS, many hospitals were uncomfortable using the device for the mapping procedure, hence the low number of claims. Note that we believe this is a glaring error in the existing claims data and another reason why TPT status should be extended for an additional four quarters.

TriSalus believes using TriNav in conjunction with this mapping procedure is important and is currently conducting two prospective, open-label clinical studies to prove that the type of catheter used to deliver the radiotracer in the mapping procedures significantly improves the delivery of radioactive microspheres during radioembolization treatment for liver cancer, in addition to the accuracy of the mapping itself (the study includes both HCC and colorectal cancer liver metastasis (CRCLM) patients). In one study (NCT05128032), TriNav is being compared to conventional microcatheters to determine the extent to which the tumor-to-normal liver ratio can be improved, which reflects both the potential for response to treatment and safety. In another study expected to open at the end of 2022, investigators will assess whether TriNav improves the ability of mapping procedures to predict Y90 delivery during treatment – an important factor in ensuring safe and effective therapeutic delivery. Once data from these studies are available and mature, we will submit to CMS for review and consideration.

HCPCS code 37243 meets the criteria for a complexity adjustment from APC 5193 (Level 3 Endovascular Procedures) to APC 5194 (Level 4 Endovascular Procedures) when billed with C1982. 2021 OPPS data shows 158 claims where HCPCS 37243 is billed with C1982, which meets the volume threshold. These claims also meet the cost threshold ($15,962) necessary for

a complexity adjustment. **A Level 4 Endovascular procedure payment would facilitate a more precise payment and ensure beneficiary access to innovative technology.**

As demonstrated above, when paired with C1982, HCPCS code 37243 is eligible for a complexity adjustment so that the code should be moved from APC 5193, Level 3 Endovascular procedures, to APC 5194, Level 4 Endovascular procedures. Additionally, as illustrated in the previous table, a Level 4 Endovascular procedure payment would accomplish several objectives:

- Placement in APC 5194 would eliminate significant underpayment as a potential barrier to access a clinically important technology that could enhance the overall procedural outcome.
- HCC is a devastating disease with substantial clinical and economic burden that is exacerbated by the lack of treatment options for patients. To date, there has been limited advancement in treatments as well as low response to immunotherapy. TACE and TARE are accepted SoC, endorsed by specialty societies, and listed in clinical practice guidelines.[3] TriSalus PEDD™ can address infusion challenges for solid tumors during TACE and TARE procedures superior to the conventional microcatheter that has been used during this procedure. TriNav can **overcome ITP and optimize flow during drug delivery in these procedures allowing for greater therapeutic uptake and reduced non-targeted delivery.**
- Providing appropriate payment for a clinically proven enhanced technology that can improve SoC for a disease area in desperate need of improved treatments.

VI. Conclusion

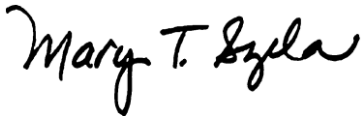
COVID severely impacted TriSalus in 2020 and 2021 due to the need for us to educate, train and support physician utilization of our technology, and physicians' ability to appropriately code and bill for those procedures during which TriNav was utilized. We respectfully request that CMS **exercise its equitable adjustment authority to grant TriSalus a one-year extension of the TPT status expiration date for TriNav**.

If CMS chooses not to extend TPT for TriNav, we ask CMS to **provide a payment adjustment by reassigning the underlying CPT code, 37243, from APC 5193 to APC 5194 when TriNav is used via a complexity adjustment. This is an alternative mechanism to ensure that patients have continued access to this important technology which can improve patient outcomes and management**.

Should CMS not have sufficient time to perform a complexity adjustment assessment prior to the release of the final rule, we ask that CMS **utilize its equitable adjustment authority to provide separate payment mimicking TPT payment while the assessment is performed**. This will ensure there are no disruptions in access to care, better support additional access to care in areas where TriNav has not yet been adopted, while also providing an opportunity for CMS to gather additional and necessary claims data regarding the frequency at which the code combinations are performed and accurate associated costs.

Thank you for the opportunity to present our views. We would happily work with CMS on any of the abovementioned issues. If you have any questions regarding our comments, please get in touch with Mary Szela at Mary.Szela@TriSalusLifeSciences.com or Dr. Steven Katz at Steven.Katz@TriSalusLifeSci.com.

Sincerely,



Mary T. Szela
President & CEO

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