

August 21 – 22, 2023

Presentation to HOP Panel

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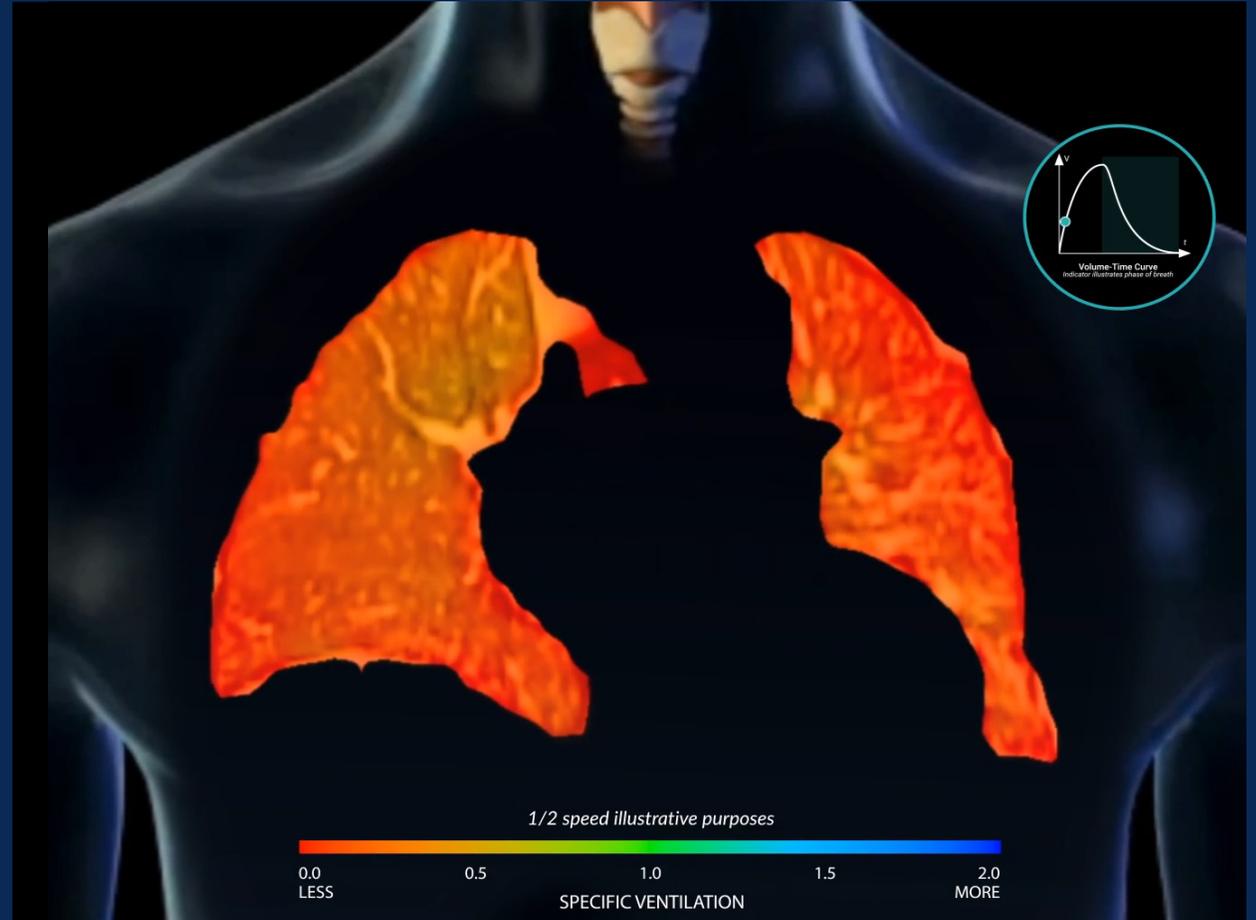


- Recommend that CMS reassign for CY 2024 CPT codes 0807T and 0808T to APC 5723 -- Level 3 Diagnostic Tests and Related Services

Overview of XV Technology

- **Patented respiratory imaging platform**
 - Understand regional air flow in the lung
 - Identify respiratory deficiencies earlier and with greater sensitivity
- **Quantitative 4D data**
 - Utilizing proven mathematical models and algorithms, XV Technology converts sequences of X ray images into four-dimensional quantitative data (three dimensional + time)
- **4D Imaging Platform**
 - Integrates with existing fluoroscopy
 - No requirement for capital investment
- **XV combines best of existing modalities:**
 - Functional insight of spirometry at a regional level
 - Comparable radiation dose to X ray
 - High detail resolution of a CT scan

XV TechnologyTM



Overview of XV Technology



What inputs are required to generate a 4DMedical XV LVAS report?

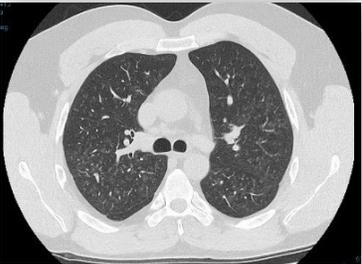
1x reference chest CT on file



Fluoroscopy of tidal breathing using 5 angles



4DMedical XV LVAS Report



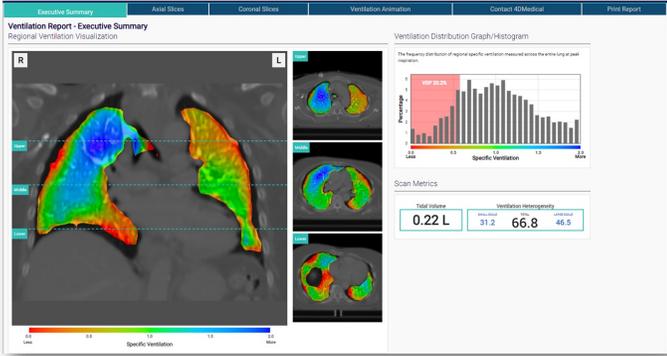
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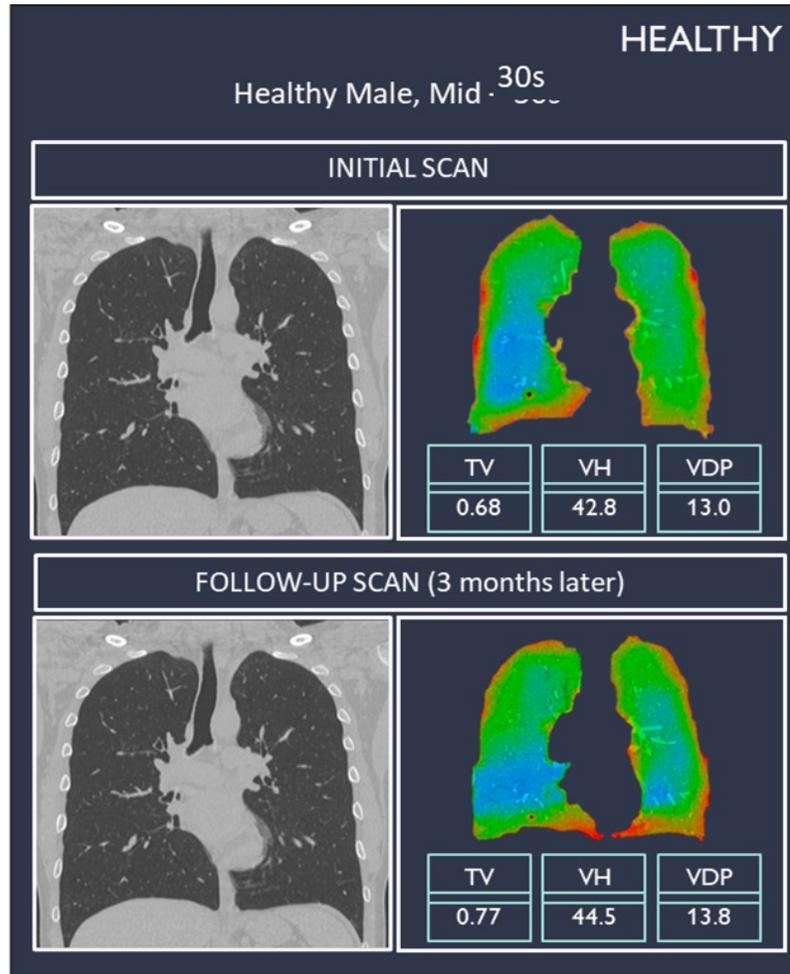
1

Validated assessment of regional lung function

2

Reliable repeatability of findings

TV: Tidal Volume
VH: Ventilation Heterogeneity
VDP: Ventilation Defect Percentage



Regional Ventilation Visualization Slices

The Regional Ventilation Visualization Slices (Axial and Coronal) indicate, through color, regional specific ventilation at peak inspiration, with 8mm spacing.

- **Red** shows regions of under ventilation
- **Green** shows regions of normal ventilation
- **Blue** depicts regions of over ventilation

Case Study: COPD

Indication

Prior biologics therapeutic for re-current exacerbation of moderate obstructive lung disease.

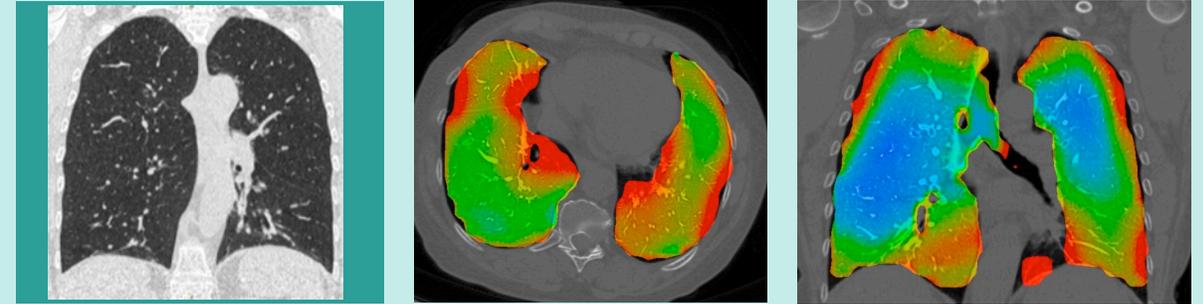
Summary

- SOB for further investigation.
- At baseline CT was unremarkable. Placed on biologics for history of exacerbation.
- Following Tx, there are functional improvements in regional ventilation indices (reduced VH and VDP). Notably, appearance of improved ventilation, specifically in the dependent areas of the right and left lungs.
- Corresponding with patient reported improvement in symptoms.

Clinical Observations

- Improved symptoms demonstrated a clinical correlation with improvements in regional ventilation function. Continued therapy with novel biologics.
- Functional assessment of regional ventilation assists in tracking response to therapy and management.

Baseline



Structural CT

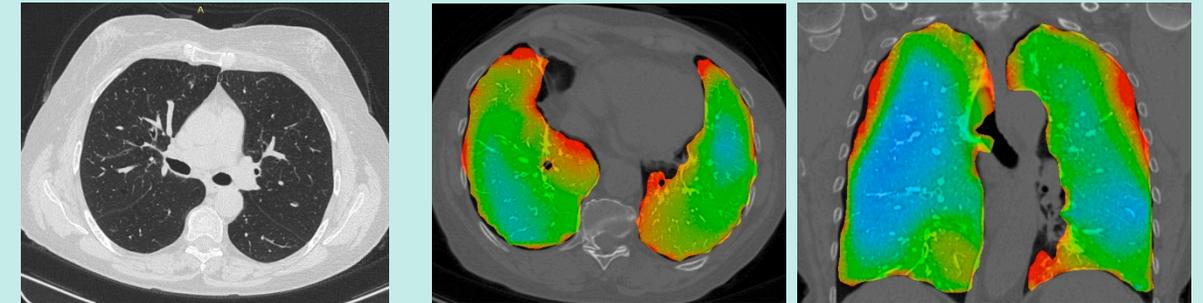
XV LVAS

TV
0.69L

VH
60.8%

VDP
18.1%

5 Months Post-Treatment



Structural CT

XV LVAS

TV
0.7L

VH
47.0%

VDP
13.4%

AMA CPT Editorial Panel issues Category III CPT Code



CPT Code	Descriptor	Effective Date	July 2023 APC Assignment	July 2023 APC Assignment
0807T	<p>Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report</p> <p>(Do not report 0807T in conjunction with 76000, 78579, 78582, 78598)</p>	July 1, 2023	5721	\$145
0808T	<p>Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; IN combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report</p> <p>(Do not report 0808T in conjunction with 71250, 71260, 71271, 76000, 78579, 78582, 78598)</p>	July 1, 2023	5722	\$280

Typical Patient (X094T)

A 72-year-old male with chronic obstructive pulmonary disease is no longer adequately controlled with medical therapy. His physician orders pulmonary ventilation analysis using software-based processing of data from cinefluorograph images in combination with previously obtained computed tomography images.

Description of Procedure (X094T)

Five cinefluorographic images of the lung are obtained for the purpose of pulmonary ventilation analysis and are uploaded to an image routing system. Acquisition of these images are included in the code and not separately reported. The image routing system then identifies corresponding images from a previously obtained computed tomography scan of the chest. The images are then transmitted to the analysis engine via standard Digital Imaging Communications in Medicine protocols for pulmonary ventilation analysis. The pulmonary ventilation analysis using specialized analysis software and advanced engineering computation is performed. All results from the pulmonary ventilation analysis are included in a structured quantitative report. The results report is then sent to a qualified health care (QHP) for review and interpretation. A QHP considers all data in the results report and dictates a medical report.

Typical Patient (X116T)

A 73-year-old male with chronic obstructive pulmonary disease is no longer adequately controlled with medical therapy. He undergoes computed tomography of the chest. His physician orders pulmonary ventilation analysis using software-based processing of data from cinefluorograph images in combination with concurrently obtained computed tomography images.

Description of Procedure (X116T)

Five cinefluorographic images of the lung and computed tomography of the chest are obtained for the purpose of pulmonary ventilation analysis and are uploaded to an image routing system. Acquisition of these images are included in the code and not separately reported. The image routing system identifies corresponding images between the cinefluorographic exam and computed tomography and transmits these images to the analysis engine via standard Digital Imaging Communications in Medicine protocols for pulmonary ventilation analysis. The pulmonary ventilation analysis using specialized analysis software and advanced engineering computation is performed. All results from the pulmonary ventilation analysis are included in a structured quantitative report. The results report is then sent to a qualified health care professional (QHP) for review and interpretation. A QHP considers all data in the results report and dictates a medical report.

Pulmonary Tissue Ventilation Analysis Procedure Components: 0807T

Components	X-Walk CPT Code	Geometric Mean Cost (2024 OPPS NPRM)
Fluoroscopic Imaging	76000	\$262
XVLVAS (SAAS) data preparation and transmission, quantification of pulmonary tissue	N/A	XVLVAS component Per analysis/report Invoice cost to Provider/Facility \$200.00
0807T -- Total Cost		\$462

CPT Code 0808T Procedure Components and Cost



Pulmonary Tissue Ventilation Analysis Procedure Components: 0808T

Components	CPT Code	Geometric Mean Cost (2024 OPPS NPRM)
Fluoroscopic Imaging [Technical]	76000	\$262
Thoracic Computed Tomography	71250	\$94
XVLVAS (SAAS) data preparation and transmission, quantification of pulmonary tissue [Technical]	N/A New Technology	XVLVAS component Per analysis/report Invoice cost to Provider/Facility \$200.00
0808T – Total Cost		\$556



CPT Codes 0807T and 0808T – CY 2024 APC Recommendations

CPT Code	Estimated HOPD Cost of Procedure Described by CPT Code	CY 2024 APC Recommendation	Geometric Mean Cost APC 5723 (2024 OPSS NPRM)	Geometric Mean Cost Range for Significant Procedures within APC 5723
0807T	\$462	5723	\$519	\$374-\$658
0808T	\$556	5723	\$519	\$374-\$658

- **4DMedical**
 - Global medical technology company focused on improving care for patients with lung disease by revolutionizing respiratory imaging and ventilation analysis
 - Flagship technology: XV Lung Ventilation Analysis Software (XV LVAS) non-invasive way of understanding regional lung motion and airflow using conventional fluoroscopic imaging modality
 - FDA Clearance May 2020; Commercialization in US and AUS
 - AMA issues CPT codes 0807T and 0808T effective July 1, 2023
- **Requesting CY 2024 APC Assignment 5723 for both CPT Codes 0807T and 0808T**
- **APC 5723 Level 3 Diagnostic Tests and Related Services with a CY 2024 OPPS NPRM payment rate of \$519**



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