

**PREVENT CANCER FOUNDATION
QUANTITATIVE IMAGING WORKSHOP**

Utilizing Quantitative Thoracic Imaging to Optimize Population Health

**AI Descriptors in the Continuum
from Labeling to Coverage and
Payment via Coding**

**Enabling Patient Access
to Healthcare Benefits of Innovation**

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PREMISE

Patient access to the benefits of AI requires clinical integration of, and payment for, services/procedures performed by Software as a Service (aka Software as a Medical Device). This framework provides descriptors for discrete and differentiable CPT codes which characterize the relative roles for device and physician/QHP.

FDA Terms

- Limitations in the terminology used to date to describe AI services in the CPT[®] code set.
- Growth in FDA-cleared software as a medical device (SaMD).
- Confusion about how best to describe work performed by the machine on behalf of the physician or other qualified health care professional.
- Need to define elements of differentiation among AI services.



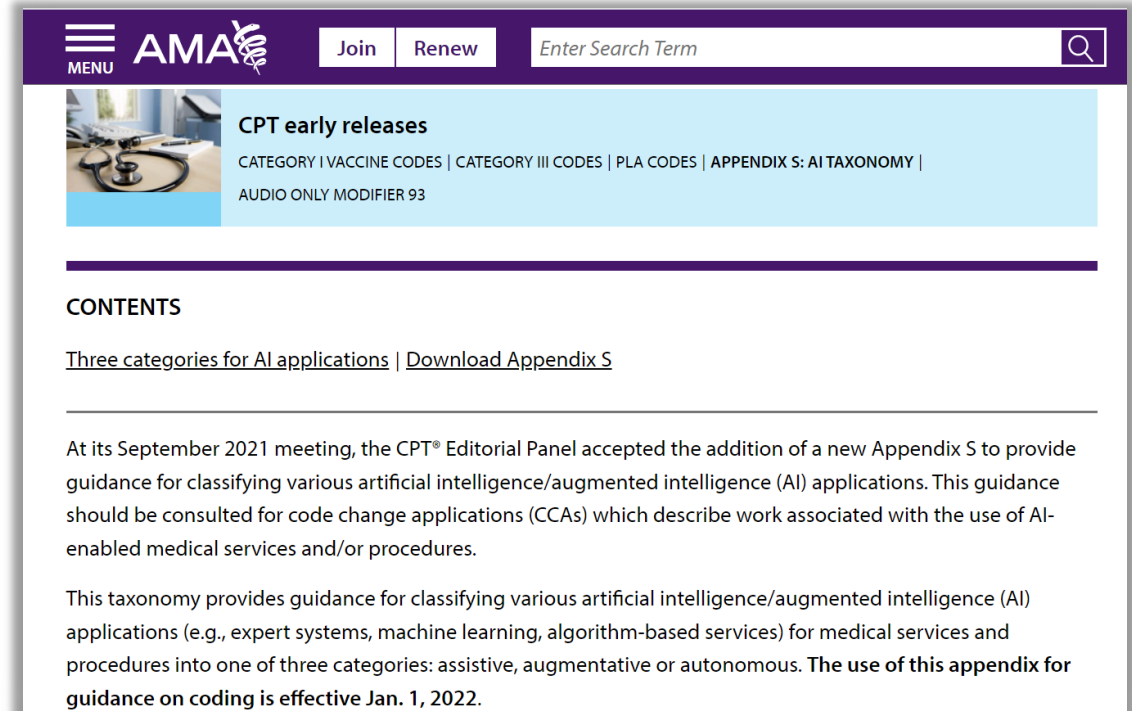
The screenshot shows the FDA website page for "Software as a Medical Device (SaMD)". The page header includes the FDA logo and "U.S. FOOD & DRUG ADMINISTRATION". The breadcrumb trail is: Home / Medical Devices / Digital Health Center of Excellence / Software as a Medical Device (SaMD). The main heading is "Software as a Medical Device (SaMD)". Below the heading, it states "Content current as of: 12/04/2018". There are social media sharing buttons for Facebook, Twitter, LinkedIn, Email, and Print. A "Subscribe to Email Updates" button is also present. The page content includes a section for "Software as a Medical Device (SaMD)" with links to "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices" and "Artificial Intelligence and Machine Learning in Software as a Medical Device". The main text explains that as technology advances, software has become an important part of all products, integrated into digital platforms. It states that Software as a Medical Device is one of three types of software related to medical devices, with the other two being software integral to a medical device and software used in the manufacture or maintenance of a medical device. The section "What is Software as a Medical Device?" is partially visible.

<https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices>

CPT® Appendix S: AI taxonomy for medical services & procedures

The AI Taxonomy provides and defines distinct categories to describe the work done by the machine on behalf of the physician based on:

- Technical features and performance of emerging AI products and services
- Effect on the work of the Physician/QHP
- Discrete components of work in order to facilitate valuation



The screenshot shows the top navigation bar of the AMA website with a purple background. It includes a 'MENU' icon, the 'AMA' logo, 'Join' and 'Renew' buttons, and a search bar with the placeholder text 'Enter Search Term'. Below the navigation bar is a light blue banner with the heading 'CPT early releases' and a list of links: 'CATEGORY I VACCINE CODES | CATEGORY III CODES | PLA CODES | APPENDIX S: AI TAXONOMY | AUDIO ONLY MODIFIER 93'. A horizontal purple line separates this banner from the 'CONTENTS' section. Under 'CONTENTS', there are two links: 'Three categories for AI applications' and 'Download Appendix S'. The main body of the page contains two paragraphs of text. The first paragraph states that at the September 2021 meeting, the CPT® Editorial Panel accepted the addition of a new Appendix S to provide guidance for classifying various artificial intelligence/augmented intelligence (AI) applications. The second paragraph explains that this taxonomy provides guidance for classifying various artificial intelligence/augmented intelligence (AI) applications (e.g., expert systems, machine learning, algorithm-based services) for medical services and procedures into one of three categories: assistive, augmentative or autonomous. It concludes that the use of this appendix for guidance on coding is effective Jan. 1, 2022.

PREMISE

The “Taxonomy of Artificial Intelligence for Medical Services and Procedures” was accepted by the CPT Editorial Panel effective January 1, 2022. It provides a framework for discrete and differentiable CPT codes which; are consistent with the features of the devices’ output, characterize interaction between the device and the physician or other qualified health care professional, and foster appropriate reimbursement. Descriptors include “Assistive”, “Augmentative”, and “Autonomous”.

By facilitating proper and consistent coding, the taxonomy enables tracking and billing as software increasingly augments the provision and intensity of medical services, thereby fostering patient, provider, and payer access to the benefits of innovation.

AI Taxonomy: Introductory language

“ This taxonomy provides guidance for classifying various artificial intelligence (AI) applications (eg, expert systems, machine learning, algorithm-based services) for medical services and procedures into one of these three categories: assistive, augmentative, and autonomous. AI as applied to health care may differ from AI in other public and private sectors (eg, banking, energy, transportation). **Note that there is no single product, procedure, or service for which the term “AI” is sufficient or necessary to describe its intended clinical use or utility; therefore, the term “AI” is not defined in the code set.** In addition, the term “AI” is not intended to encompass or constrain the full scope of innovations that are characterized as “work done by machines.” Classification of AI medical services and procedures as assistive, augmentative, and autonomous is based on the clinical procedure or service provided to the patient and the work performed by the machine on behalf of the physician or other qualified health care professional (QHP) ”



• ASSISTIVE

• AUGMENTATIVE

• AUTONOMOUS

ASSISTIVE

The work performed by the machine for the physician or other qualified health care professional is assistive when the machine **detects** clinically relevant data without analysis or generated conclusions. Requires physician or other qualified health care professional interpretation and report.

AUGMENTATIVE

The work performed by the machine for the physician or other qualified health care professional is augmentative when the machine **analyzes and/or quantifies** data in a clinically meaningful way. Requires physician or other qualified health care professional interpretation and report.

AUTONOMOUS

The work performed by the machine for the physician or other qualified health care professional is autonomous when the machine automatically **interprets data and independently generates clinically relevant conclusions** without concurrent physician or other qualified health care professional involvement. An autonomous medical service includes interrogating and analyzing data. The work of the algorithm may or may not include acquisition, preparation, and/or transmission of data. The clinically relevant conclusion may be a characterization of data (eg, likelihood of pathophysiology) to be used to establish a diagnosis or to implement a therapeutic intervention. There are three levels of autonomous AI medical services and procedures with varying physician or other qualified health care professional involvement:

I.

The autonomous AI draws conclusions and offers diagnosis and/or management options, is contestable and **requires physician or other qualified health care professional action to implement.**

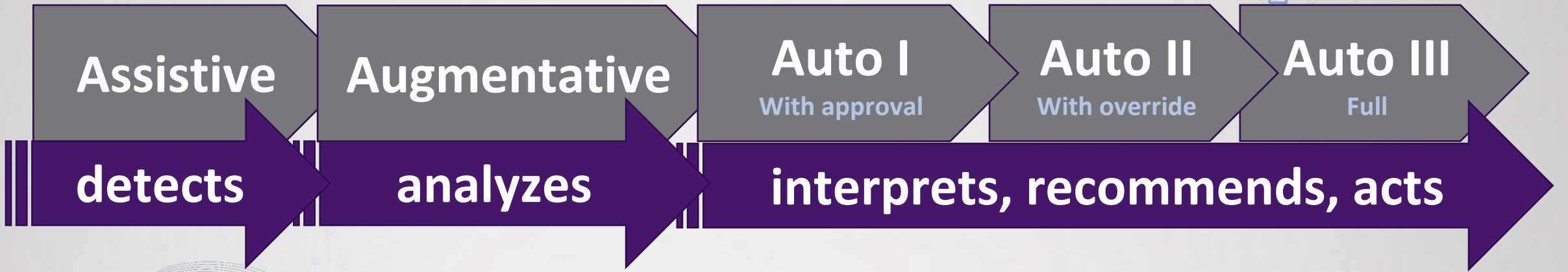
II.

The autonomous AI draws conclusions and initiates diagnosis and/or management options with alert/opportunity for override, **may require physician or other qualified health care professional action to implement.**

III.

The autonomous AI draws conclusions and initiates management, **requires physician or other qualified health care professional action to contest.**

Service Components	Assistive	Augmentative	Autonomous
Primary Objective	Detects clinically relevant data	Analyzes and/or quantifies data in a clinically meaningful way	Interprets data and independently generates clinically meaningful conclusions
Provides Independent diagnosis and/or management decision	No	No	Yes
Analyzes Data	No	Yes	Yes
Requires Physician or other qualified health care professional Interpretation and Report	Yes	Yes	No
Examples in CPT code set	Computer-Aided Detection (CAD) Imaging (77048, 77049, 77065-77067, 0042T, 0174T, 0175T)	Magnetic Resonance Spectroscopy (0612T), external processing of imaging data sets	Retinal Imaging (92229)



How has the AI Taxonomy been used so far?

CPT Code 92229 is the only category I code that currently fits into the category of autonomous.

- 92229 Imaging of retina for detection or monitoring of disease; point-of-care automated analysis and report, unilateral or bilateral



CPT® Editorial Summary of Panel Actions February 2022

Tab #	Name	Code #	Request-Description	Effective Date
25	Retinal Imaging - Revise 92229	▲92229	Accepted revision of code 92229 by removing the term "automated" and replacing it with "autonomous"	January 2023

The background is a dark blue gradient with intricate, glowing white and light blue digital patterns. These patterns consist of thin, interconnected lines forming a complex network, with small squares and rectangles scattered throughout, resembling a circuit board or data flow visualization. The patterns are more dense and prominent in the upper and lower portions of the frame, framing the central text.

CMS on AI

SaaS According to CMS; OPPS Solicitation Specific Questions

1. How to identify services that should be separately recognized as an analysis distinct from both the underlying imaging test or the professional service paid under the PFS;
2. How to identify costs associated with these kinds of services;
3. How these services might be available and paid for in other settings (physician offices, for example); and
4. How CMS should consider payment strategies for these services across settings of care.

Meeting the Moment: Addressing Barriers and Facilitating Clinical Adoption of Artificial Intelligence in Medical Diagnosis

Although there are not direct reimbursement channels for many types of AI-DDS tools ... CMS reimburses physician office payments through the Medicare Physician Fee Schedule (MPFS). Within MPFS, payment details are specified via the Current Procedure Terminology (CPT), maintained by the American Medical Association (AMA). CPT codes denote different procedures and services provided in the clinic. New AI-CDS/ DDS systems that receive approval for reimbursement by CMS may be assigned a CPT code, as was done in 2020 for IDx-DR, an autonomous AI tool for the diagnosis of diabetic retinopathy (Digital Diagnostics, 2022).

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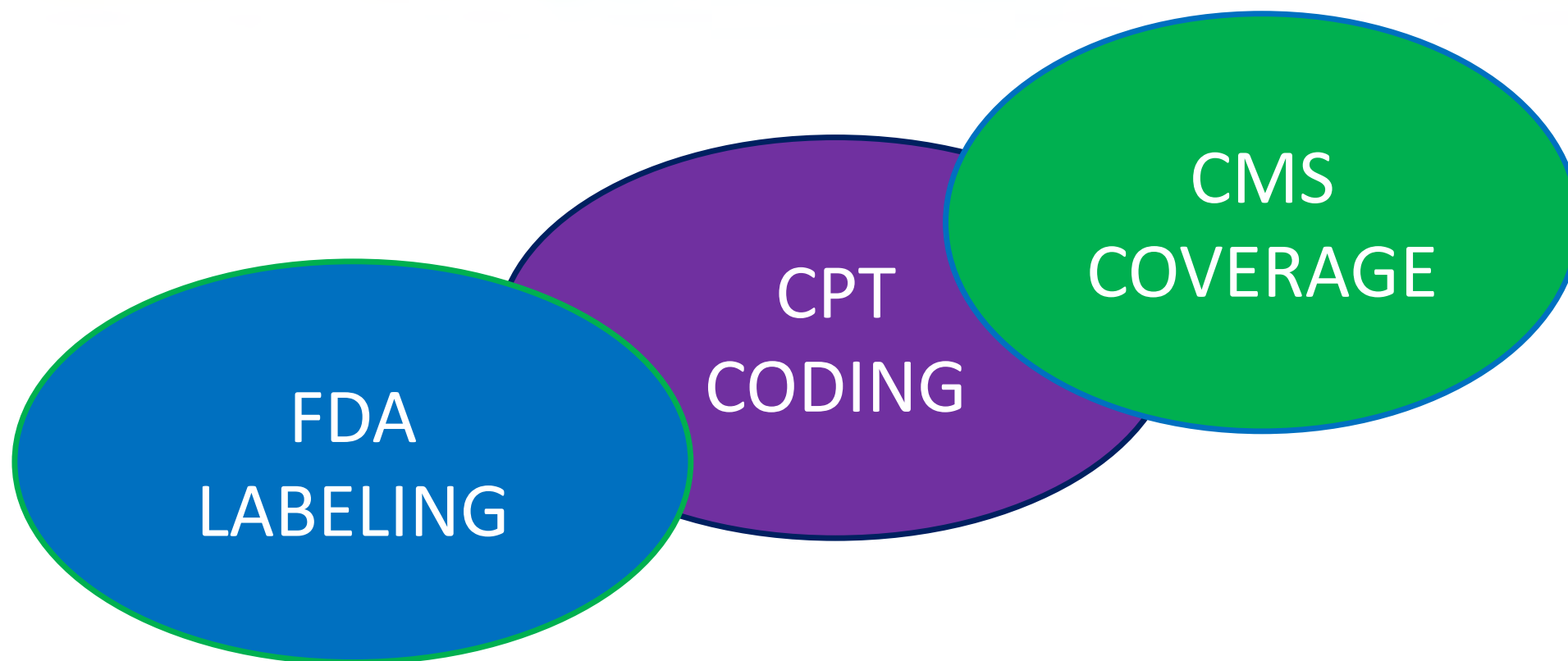
CMS Criteria for Separate Payment FFRCT is not Processing

The CY 2008 OPPI/ASC final rule states that image processing covers “supportive dependent services to process and integrate diagnostic test data in the development of images, indicating that an **image processing service must;**

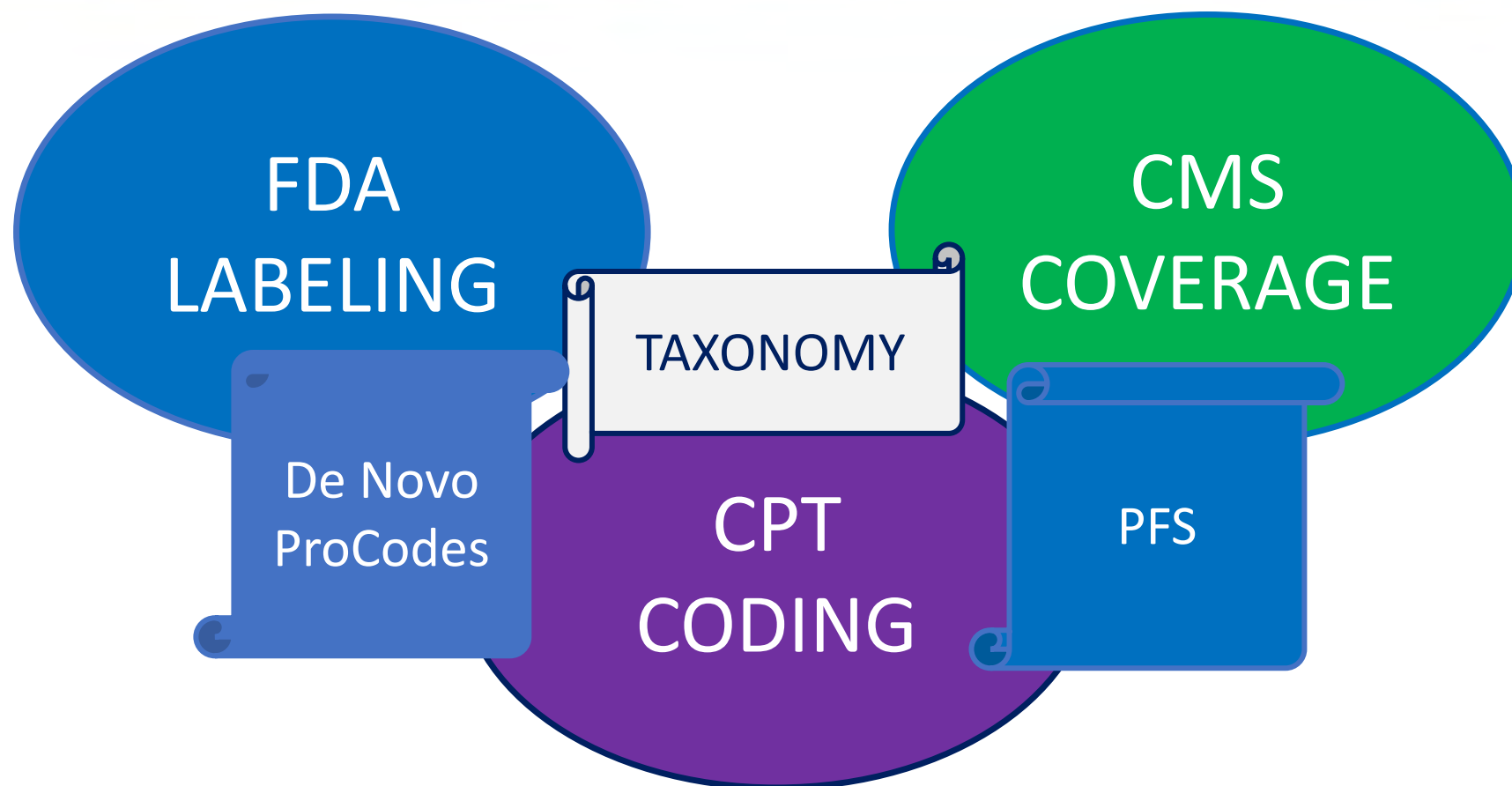
help develop or
otherwise **visually enhance an image**

...the FFRCT service does neither [and therefore is not processing]

A Harmonized Lexicon Would be Ideal



A Harmonized Lexicon Would Facilitate Labeling, Coding, Valuation, Coverage, and Payment



WHITE
SPACE
=
CONFUSION

THANK YOU