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Treatment of FFR_{CT} in the CY 2024 PFS Rule

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Agenda

1. Introductions

2. Brief overview of Coronary Artery Disease (CAD) and its impact on Medicare beneficiaries

3. Overview of the Fractional Flow Reserve derived from Computed Tomography (FFR_{CT}) service and its clinical benefits

4. Request that the Office of Management and Budget (OMB) work with the Centers for Medicare & Medicaid Services (CMS) to continue the crosswalk established in CY 2022 for Medicare physician fee schedule (PFS) payment for FFR_{CT} in CY 2024

Improving cardiac care for Medicare beneficiaries

1. **Coronary Artery Disease (CAD) is the most common type of heart disease and the leading cause of death in the United States (accounting for 1 out of every 3 deaths)[1]**

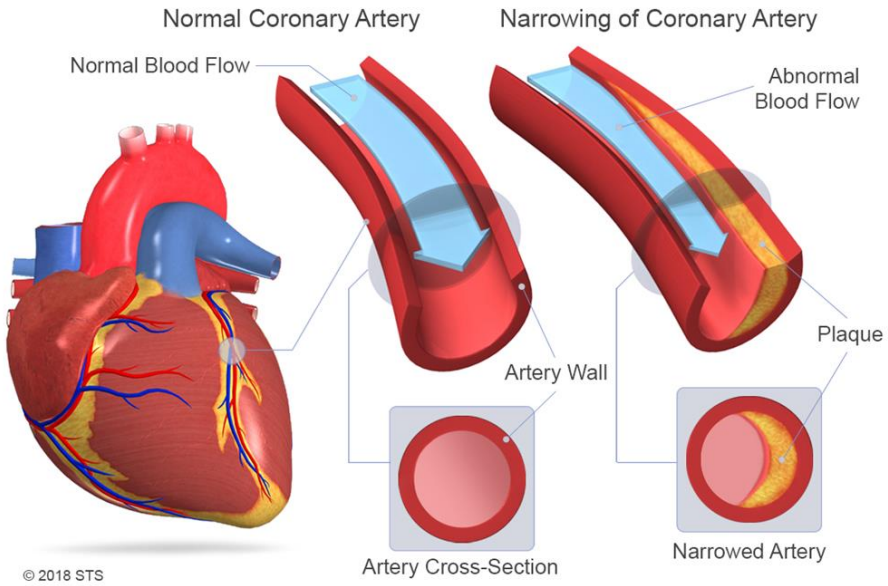
2. **Cardiac care today leads to suboptimal outcomes and high costs for Medicare beneficiaries**
   - 20-30% of stress tests are false negatives, missing the opportunity to diagnose and treat critical disease[2]
   - 55% of patients sent for invasive testing (cost = $2,958) have no significant disease[3]
   - Stress testing and stenting for CAD led to 38% of low-value spend identified by MedPAC (~ $2.5 billion per-year)[4]

3. **A pathway utilizing coronary CT angiography (CTA) and Fractional Flow Reserve derived from CT (FFR_{CT}) is recommended by a new American College of Cardiology (ACC) and American Heart Association (AHA) led guideline[5]**
   - This pathway leads to a 41% lower rate of death and heart attack, a 60% reduction in invasive procedures, and cost-savings of > $3,100 per-patient[6]
   - The prospective, randomized controlled PRECISE trial demonstrated this pathway led to a 70% reduction in the composite endpoint of death, heart attack, or unnecessary catheterization[7]
   - Full adoption by Medicare could save the program ~$3.0 billion annually

1. Yelin, et al. Am Heart Assoc, 2017. 2. Arbab-Zadeh, Heart Int, 2012. 3. Patel, et al. N Engl J Med, 2010.
4. Healthcare Spending and the Medicare Program. MedPAC, June 2017.
5. Gulati, M. et al. Circulation, 2021. 6. Douglas, P. et al. J Am Coll Cardiol, 2016. 7. PRECISE trial – Presented at AHA 2022.

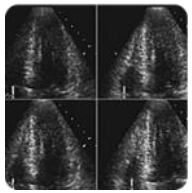
Coronary Artery Disease (CAD)

- Most common type of heart disease and the leading cause of death in the United States (1 out of every 3 deaths)[1]
- Cardiovascular mortality is 33% higher for Black adults[2] and nearly 20% higher for Native American adults compared to White adults[3].
- CAD occurs when the arteries that supply blood to the heart become narrowed allowing less blood to flow through the arteries.
- This can lead to chest pain (angina) or a heart attack.

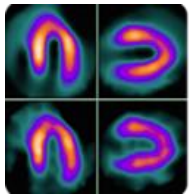


1. CDC Division for Heart Disease and Stroke Prevention, 2019; American Heart Association, 2017; Yelin, et. al.
2. Lloyd-Jones, D., et al., Heart disease and stroke statistics - 2009 update. Circulation, 2009.
3. Veazie, M., et al., Trends and disparities in heart disease mortality among American Indians/Alaska Natives, 1990-2009. Am J Public Health, 2014.

Noninvasive stress tests have limited utility



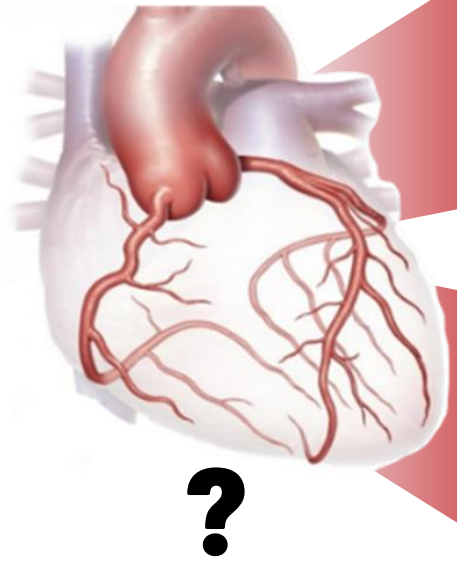
Stress Echo



SPECT

Treadmill

No direct information on disease in the coronary arteries



AVOIDABLE LAYERED TESTING

55% FALSE POSITIVES:
patients sent for an invasive angiogram have **no obstructive CAD**[1]

UNDETECTED DISEASE

20-30% FALSE NEGATIVES:
patients sent home with their **undetected coronary disease**[2]

1. Patel, et al. N Engl J Med 2010. Patel, et al. AHJ 2014. Danad, et al. JAMA Cardiology 2017.
2. Arbab-Zadeh, Heart Int 2012. Yokota, et al. Neth Heart J 2018. Nakanishi, et al. J Nucl Cardiol 2018.

2017 MedPAC report: stress testing for CAD is a low-value service

Chart 5-6. Between 34 and 72 low-value services provided per 100 FFS beneficiaries in 2014; Medicare spent between $2.4 billion and $6.5 billion on these services

	Broader version of measures			Narrower version of measures		
Measure	Count per 100 beneficiaries	Share of beneficiaries affected	Spending (millions)	Count per 100 beneficiaries	Share of beneficiaries affected	Spending (millions)
Imaging for nonspecific low back pain	12.0	8.9%	$232	3.4	3.1%	$66
PSA screening at age ≥75 years	9.0	6.2	79	5.1	4.2	44
Colon cancer screening for older adults	8.0	7.5	405	0.3	0.3	3
Spinal injection for low back pain	6.6	3.3	1,261	3.4	2.0	643
Carotid artery disease screening in asymptomatic adults	5.1	4.6	268	4.2	3.8	221
Preoperative chest radiography	4.6	4.1		1.1	1.1	17
PTH testing in early CKD	4.5	2.6	83	3.9	2.3	71
Stress testing for stable coronary disease	4.3	4.1	1,198	0.5	0.5	137
T3-level testing for patients with hypothyroidism	3.8	2.2	23	3.8	2.2	23
Head imaging for headache	3.6	3.3	242	2.4	2.2	160
Cervical cancer screening at age >65 years	2.2	2.2	44	1.9	1.9	39
Homocysteine testing in cardiovascular disease	1.5	1.2	12	0.4	0.3	3
Head imaging for syncope	1.2	1.1	78	0.8	0.7	51
Preoperative echocardiography	0.8	0.8	62	0.2	0.2	19
Preoperative stress testing	0.6	0.6	177	0.2	0.2	60
Screening for carotid artery disease for syncope	0.6	0.6	33	0.4	0.4	23
CT for rhinosinusitis	0.6	0.5	39	0.2	0.2	17
Vitamin D testing in absence of hypercalcemia or decreased kidney function	0.5	0.4	8	0.5	0.4	8
Imaging for plantar fasciitis	0.5	0.4	9	0.4	0.3	6
BMD testing at frequent intervals	0.4	0.4	9	0.3	0.3	6
Cancer screening for patients with CKD on dialysis	0.4	0.3	9	0.1	0.1	1
PCI/stenting for stable coronary disease	0.3	0.3	1,284	0.1	0.1	216
Arthroscopic surgery for knee						

Findings from the Report

- Low-value services were defined as services with little or no clinical benefit, or the risk of harm outweighs potential benefit
- Stress testing and Stenting for stable CAD accounted for 38% ($2.5 billion) of low-value spend identified by MedPAC

1. Healthcare Spending and the Medicare Program. MedPAC, June 2017.

A better pathway for Medicare beneficiaries with suspected CAD

Informed Clinical Decision:
Is there coronary artery disease with a 30-90% stenosis by coronary CTA?

YES
~30% of CTAs

NO
~70% of CTAs

Informed Clinical Decision:
(Without additional tests)

Conservative management

Invasive management

Decision made and care delivered using **optimal** imaging and **physiologic** information

FFR_{CT}: PROVEN RESULTS

Far past the 'early innovation' stage, the CCTA + FFR_{CT} pathway has been extensively studied, is supported by the **ACC/AHA Chest Pain Guidelines**, and is being rapidly adopted nationwide.

500+ peer-reviewed publications

170K+ patients served

98% of lives covered
100% of Medicare, > 95% of Commercial Payers

~80% of the top 50 US Heart Hospitals have adopted the CCTA + FFR_{CT} pathway*

*As designated by US News & World Report. Jan 2022

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CTA and FFR_{CT} pathway is highlighted in a new society guideline

The CTA and FFR_{CT} pathway is recognized in the 2021 ACC and AHA Guideline as the frontline pathway to aid clinicians in diagnosing and guiding treatment decisions in patients with suspected or known CAD[1].

Clinical studies have demonstrated that use of the CTA and FFR_{CT} pathway:

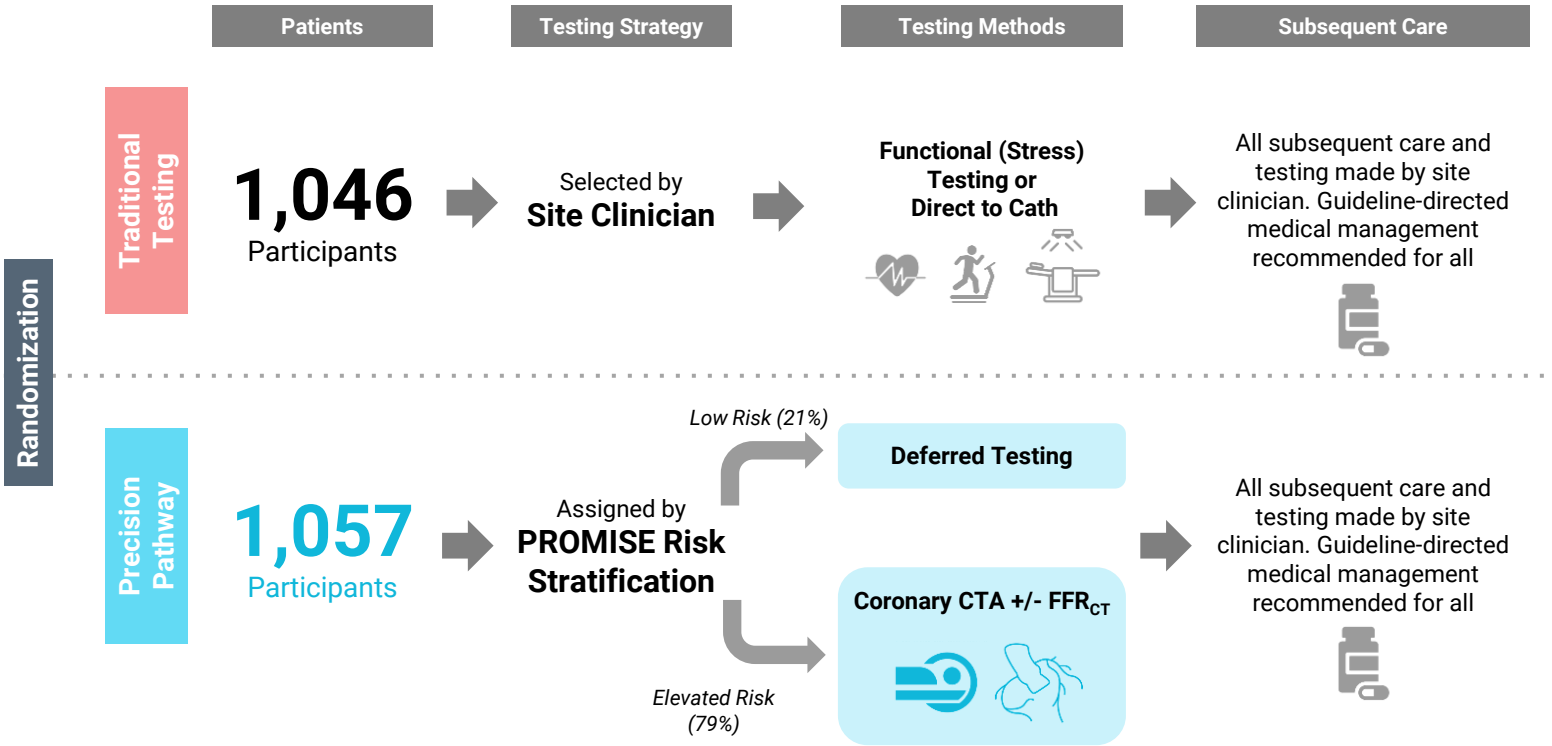
- Leads to a 41% lower rate of death and heart attack[2]
- Allows clinicians to cancel 61% of planned invasive procedures[3]
- Saves the Medicare program more than $3,100 per-patient[3]
- The prospective, randomized controlled PRECISE trial demonstrated this pathway led to a 70% reduction in adverse clinical events (death, heart attack, or unnecessary invasive catheterization)[4]

AMERICAN COLLEGE of CARDIOLOGY

American Heart Association®

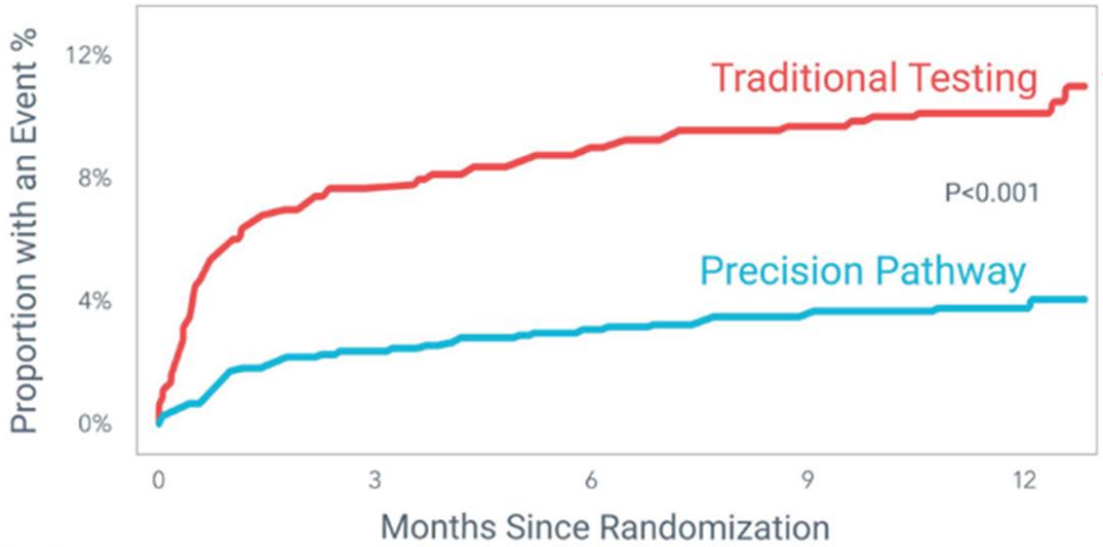
1. Gulati, et al. 2021 Chest Pain Guideline. J Am Coll Cardiol.
2. Newby, et al. N Engl J Med 2018.
3. Douglas, et al. J Am Coll Cardiol, 2016.
4. PRECISE trial – Presented at AHA 2022.

PRECISE is the 1st global, prospective, randomized control trial comparing the diagnostic and treatment pathways for stable chest pain



PRECISE trial - Presented at AHA 2022

The Precision Pathway is superior to Traditional Testing at 1 year



Number at risk					
Precision Pathway	1057	997	971	945	431
Traditional Testing	1046	922	898	869	421

70%

Reduction in the primary endpoint

PRECISE trial - Presented at AHA 2022

Broad adoption of CTA and FFR_{CT} will save the Medicare program more than $3.0 billion annually and reduce out-of-pocket costs for Medicare beneficiaries

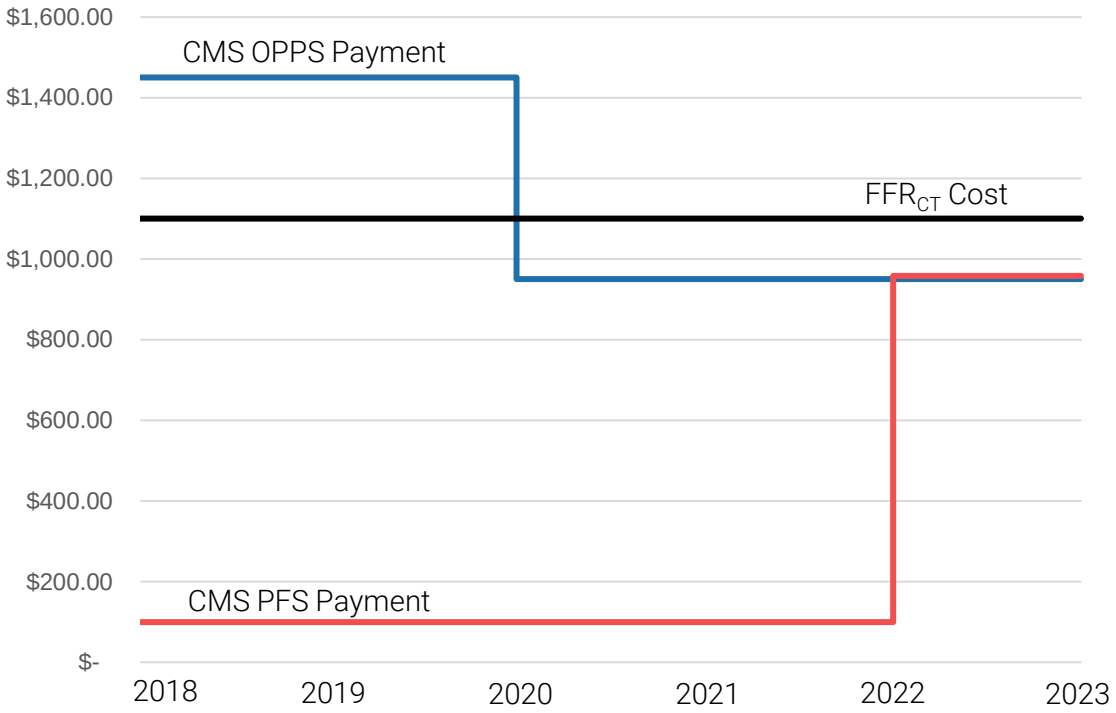
- Moving from SPECT testing, the predominant form of stress test used for Medicare beneficiaries with chest pain and suspected CAD, to CTA as a first line test could save the Medicare system more than $1.7 billion per-year.

- Utilizing FFR_{CT} as appropriate could enable physicians to cancel > 60% of planned invasive procedures leading to additional savings of over $1.3 billion per-year.

- In total, Medicare could realize annual cost savings of more than $3.0 billion per-year.

Please see slide 18 in the appendix for a detailed analysis of the potential cost savings.

CMS has recognized the novelty of FFR_{CT} and implemented appropiate payment policy



2021 OPPS Final Rule:[1]

HeartFlow is one of the first procedures utilizing artificial intelligence to be separately payable in the OPPS, and providers are still learning how to accurately report their charges to Medicare when billing for artificial intelligence services.

2021 PFS Final Rule:[2]

While we agree that the costs for AI applications should be accounted for in payment, AI applications are not well accounted for in our PE methodology.

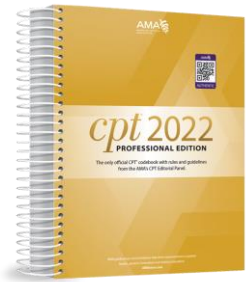
Our recent reviews of the overall cost for the [FFR_{CT}] service… have shown the costs to be similar, to the costs reflected in payment under the CY 2021 OPPS final rule for CPT code 0503T.

1. 85 Fed. Reg. 85943 (Dec. 29, 2020).
2. 85 Fed. Reg. 84630 (Dec. 28, 2020).

FFR_{CT} Category I Conversion Process

A Category I Current Procedural Terminology (CPT)* Code is coming

- The CPT Editorial Panel accepted the addition of code 7X005 to report non-invasive estimate of coronary fractional flow reserve (FFR_{CT}) derived from *augmentative* software analysis of the dataset from a CTA[1]
  - Code language is expected to include physician interpretation and report
- 7X005 will replace four Category III CPT codes (0501T – 0504T) that were previously used to describe components of the FFR_{CT} service
- This is the first CPT code to use language from CPT Appendix S: AI taxonomy for medical services & procedures[2], used to provide guidance for classifying various artificial intelligence (AI) applications
- The new code will go into effect January 1, 2024



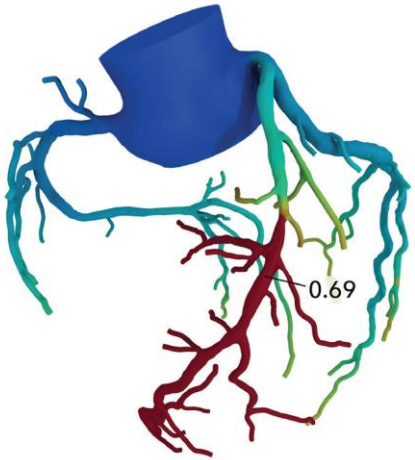
1. https://www.ama-assn.org/system/files/september-2022-cpt-summary-panel-actions.pdf
2. https://www.ama-assn.org/practice-management/cpt/cpt-appendix-s-ai-taxonomy-medical-services-procedures

Category 1 Code Conversion Initiates First Valuation of an AI-based Healthcare Service

Category III CPT Codes
(Temporary Codes)

Although CMS rarely sets payment for Category III Codes in the PFS, in 2022 they established a national payment rate for FFR_{CT} because[1]:

- Stakeholders were concerned with low and variable payment rates established by the Medicare Contractors (MACs)
- Tests such as FFR_{CT} use technologies that are not well accounted for in PFS pricing methodology
- Costs for the service are similar between the hospital outpatient & physician office settings



Category 1 CPT Codes
(Permanent Codes)

- New Category I CPT code created for FFR_{CT} effective January 1, 2024, triggering one of the first valuations of an AI-based healthcare service
- HeartFlow is concerned about beneficiary access to FFR_{CT} given the ambiguity regarding valuation of AI services through the AMA process and the CMS PFS methodology
- CMS maintains ultimate authority over payment rates under the PFS

1. 86 Fed. Reg. 64999, 65039-41 (Nov. 19, 2021).

Our ask of OMB and CMS:

Continue the crosswalk payment for the technical component of the FFR_{CT} service to a code that matches payment in the hospital outpatient setting as CMS did for CY 2022 & 2023.

- **We are concerned that the prevailing PFS payment methodology does not align with the physician resources associated with the FFR_{CT} service.**

- CMS intervened and set national payment in CY 2022 to enable access for beneficiaries, understanding that costs for the FFR_{CT} service are similar across the physician office and hospital outpatient settings. We have asked CMS to maintain the payment rate for FFR_{CT} in the PFS at a level comparable to payment in the hospital outpatient setting.

- Under the PFS methodology, even accepting the FFR_{CT} cost as direct practice expense results in a rate that could significantly reduce payment and restrict beneficiary access, undercutting past CMS actions in setting payment for the service.


Thank You!
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Broad adoption of CTA and FFR_{CT} will save the Medicare program more than $3.0 billion annually and reduce out-of-pocket costs for Medicare beneficiaries

Savings Attributed to Adoption of CTA

	Hospital (OPPS)	Physician Office (PFS)
Current CMS Volumes		
SPECT Annual Volume[1]	920,000	1,100,000
SPECT Medicare Rate (2021)	$1,335[2]	$780[3]
SPECT Annual Spend	$1,228,200,000	$858,000,000
If SPECT is converted to CTA as first test for CAD:		
CTA Medicare Rate (2021)	$182[2]	$182[4]
CTA Annual Spend if converted	$167,440,000	$200,200,000
Annual Cost Savings	$1,060,760,000	$657,800,000
Non-Invasive Annual Cost Savings:	**$1,718,560,000**	

Savings Attributed to Reduced Use of Invasive Testing

Annual Invasive Tests[5]	357,000
FFR_{CT} Medicare Cost Savings[6]*	$3,659
Invasive Annual Cost Savings:	**$1,306,263,000**

*Includes cost of FFR_{CT} at $950

Savings Attributed to Adoption of CTA + Savings Attributed to Reduced Invasive Testing = Total Annual Cost Savings of $3,024,823,000.

1. Medicare Provider Utilization and Payment Data
2. CMS CY 2022 OPPS Rule (CMS-1753-F)
3. https://www.cms.gov/medicare/physician-fee-schedule/search - CPT code 78452, A9500 (2 doses), 93015 (PFS pays each of these codes required for SPECT separately).
4. https://www.cms.gov/medicare/physician-fee-schedule/search - CPT code 75574
5. Estimated from 2018 NCDR invasive coronary angiogram data.
6. Douglas, et al. J AM Coll Cardiol, 2016.