The “Packaged Payment” Problem

11 June 2020

Privileged & Confidential

Introduction

- CMS 2008 decision to package costs of Diagnostic Radiopharmaceuticals can significantly impact patient access to higher cost, lower volume treatment
  - Burden to beneficiaries who are traveling to the decreasing number of facilities that are performing important nuclear medicine procedures
  - Stifles innovation and expansion in the nuclear medicine community as costs for new diagnostic radiopharmaceuticals are not covered after pass-through ends
- Many newer diagnostic radiopharmaceuticals provide important, medical, information impacting patient care
- CMS ignored the recommendations of its own Advisory Committee in 2008; the Committee's predictions of harm to utilization have unfortunately come true
- CMS has the authority in the Proposed Rule to separately pay for imaging drugs in OPPS – OIRA should encourage this change

What is the Impact of the CMS Drug Packaging Policy?

- Newer low volume, higher cost Diagnostic Radiopharmaceuticals for more accurate diagnosis are packaged with significantly lower cost drugs
- As a result, in most cases, the cost of the drug exceeds the reimbursement of the entire procedure
- Hospitals cannot afford to, and won't, take a significant loss every time the procedure is performed
- **Hospitals no longer offer tests, so patients lose access to treatment and diagnostic radiopharmaceuticals used to help support differential diagnosis and appropriate treatment**

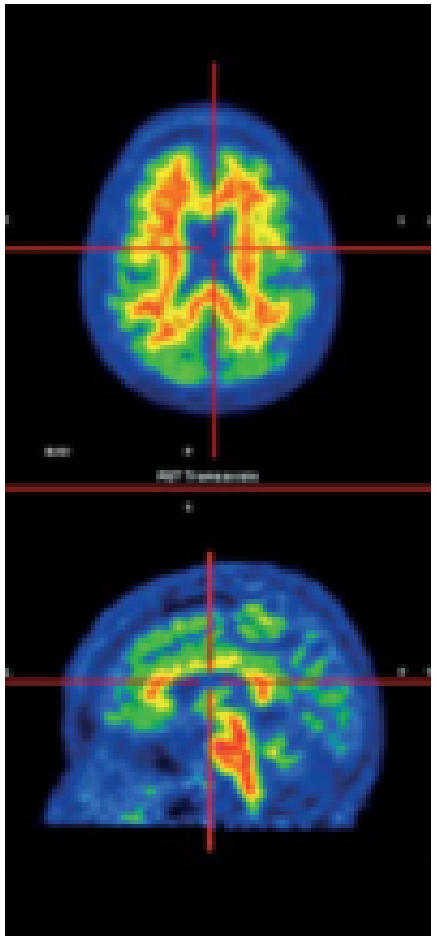
Parkinson's Patient Impact[1-7]

- **Americans living with an uncertain diagnosis: 120,000**
- **Above patients with access to diagnostic radiopharmaceutical: 100,000**
- **Total # of hospitals in U.S.: 3,173**
- **Total # of hospitals in U.S. offering access to diagnostic radiopharmaceutical: 283**

References: 1. Van Den Eeden et al. Incidence of Parkinson's disease: variation by age, gender, and race/ethnicity. *Am J Epidemiol.* 2003;157:1015-1022. **2.** Mayeux et al.1988-1993: Parkinson's Disease, 2nd Edition. CRC Press by R. F. Pfeiffer. **3.** Bower et al. 1976-1990: Parkinson's Disease 2nd Edition CRC Press by R. F. Pfeiffer. **4.** Allison et al. Geographic and ethnic variation in Parkinson disease: a population-based study of US Medicare Beneficiaries. *Neuroepidemiology*. 2010;34:143–151. **5.** Rajput et al. Epidemiology of parkinsonism: incidence, classification, and mortality. *Ann Neurol.* 1984;16:278-282. **6.** Jain S et al. Common misdiagnosis of a common neurological disorder: how are we misdiagnosing essential tremor? *Arch Neurol*. 2006;63:1100-1104. **7.** Sixel-Doring F et al. The role of 123I-FP-CIT-SPECT in the differential diagnosis of Parkinson and tremor syndromes: a critical assessment of 125 cases. *J Neurol*. 2011;258:2147-2154.

Radiopharmaceuticals

- Drugs used in imaging to provide more detailed pictures to help see ***what's happening*** inside the body
- Used by physicians to see ***how the body is functioning***, as well as the body's chemical and biological processes
- Identify ***abnormalities,*** *in some cases*, before symptoms are apparent with other diagnostic tests



How they Help

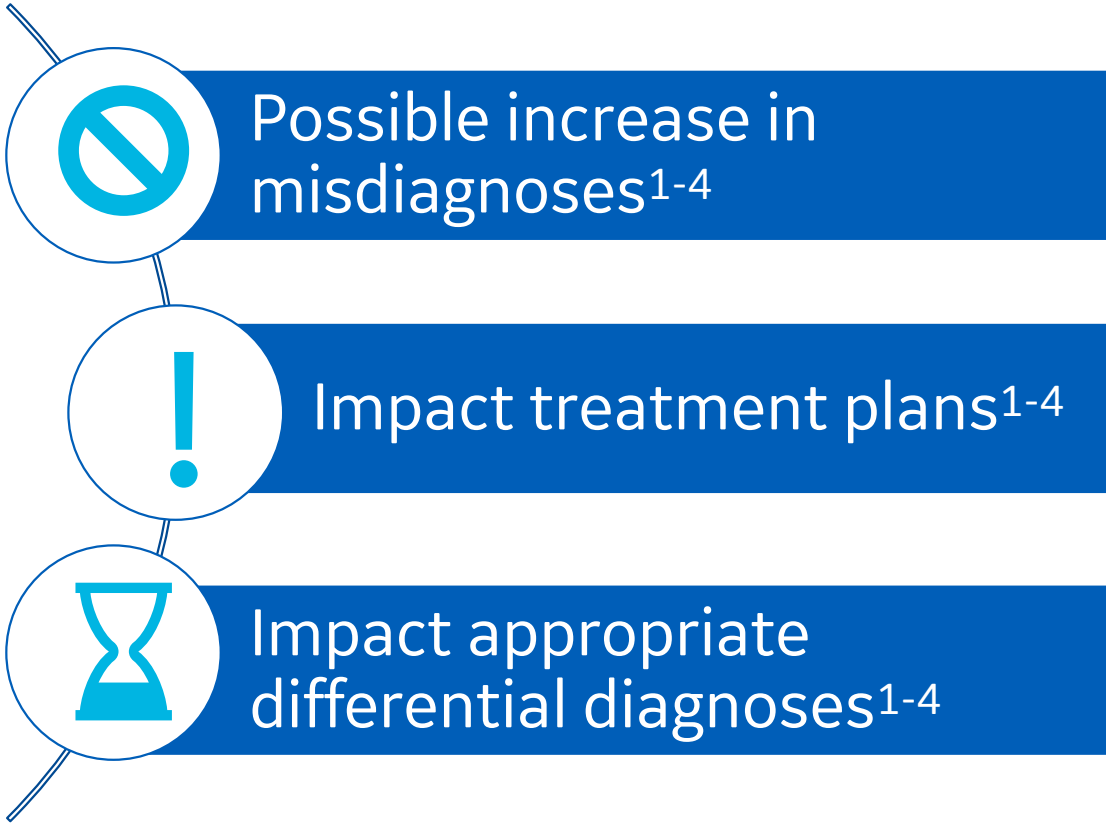
- ***More than 20 million Americans*** received a radiopharmaceutical during their diagnostic evaluation[1]
- Results from imaging may help aid in diagnoses and give patients, families and their doctors information to help support and address questions and develop a care pathway

Diseases in which radiopharmaceuticals may aid in diagnosis include:

- Alzheimer's disease
- Brain disorders
- Cancers
- Epilepsy
- GI disorders
- Heart disease
- Kidney disorders
- Lung disorders
- Lymphoma
- Melanoma
- Parkinson's disease
- Thyroid disorders

[1]. https://www.snmmi.org/ClinicalPractice/content.aspx?ItemNumber=4825. Accessed on 04/28/2020.

Lack of Access to Radiopharmaceuticals



- Current regulations are creating a ***disincentive for hospitals to offer these tests***
- This means ***patients must travel farther for care – if they can get it at all***
- Lack of access can have ***consequences for patients***

1.De Wilde, Arno, van der Flier, Wiesje, Pelkmans, Wiesje, et al. *JAMA Neurol.* 2018;75(9):1062-1070. doi:10.1001/jamaneurol.2018.1346. 2. Barthel H, Sabri O. Clinical use and utility of amyloid imaging. Journal of Nuclear Medicine. 2017. 58(11):1711-1717. PMID: 28818990.. 3.De Wilde A, van der Flier WM, Pelkmans W et al. Association of Amyloid Positron Emission Tomography With Changes in Diagnosis and Patient Treatment in an Unselected Memory Clinic Cohort -The ABIDE Project. JAMA Neurology. 2018. Sep 1;75 (9):1062-1070. 4.Rabinovici GD, Gatsonis C, Apgar C, Chaudhary K, Gareen I, Hanna L, et al. Association of Amyloid Positron Emission Tomography with subsequent change in clinical management among medicare beneficiaries with mild cognitive impairment or dementia. JAMA 2019; 321:1286–94.

Where Are Diagnostic Radiopharmaceuticals Used in Medicine Today?

HCPCS Code	2020 Long Descriptor
A9584	Iodine i-123 ioflupane diagnostic, per study dose, up to 5 millicuries
A9582	Iodine i-123 iobenguane, diagnostic, per study dose, up to 15 millicuries
A9586	Florbetapir f18, diagnostic, per study dose, up to millicuries
A9515	Choline C-11, diagnostic, per study dose
A9587	Gallium ga-68, dotate, diagnostic, 0.1 millicurie
A9588	Fluciclovine f-18, diagnostic, 1 millicurie
Q9982	Flutemetamol F18, diagnostic, per study dose, up to 5 millicuries
Q9983	Florbetaben F18, diagnostic, per study dose, up to 8.1 millicuries

Why Did CMS Package Diagnostic Radiopharmaceuticals?

ADVISORY COMMITTEE PROPOSAL

Committee recommended that 'CMS set the packaging threshold for diagnostic radiopharmaceuticals at a median cost of $200 per day, and that CMS continue to pay for diagnostic radiopharmaceuticals that cost more than $200 using the current methodology'.[1]

CMS REJECTION AND RESPONSE

'We expect that packaging would encourage hospitals to use the most cost efficient diagnostic radiopharmaceutical products that are clinically appropriate.'[2]

FACT: THERE ARE NOT ALTERNATIVE PRODUCTS IN ALL CASES

'We anticipate that hospitals would continue to provide care that is aligned with the best interests of the patient.' [2]

FACT: HOSPITAL PURCHASING DEPARTMENTS ARE REMOVED FROM CONSIDERING THE PATIENT CARE FACTORS AND ARE GENERALLY UNWILLING TO LOSE MONEY ON THESE PROCEDURES

'As we indicated in the proposed rule, we do not believe that our packaging proposal would limit beneficiaries' ability to receive clinically appropriate diagnostic procedures.' [2]

FACT: THE OPPOSITE IS HAPPENING

1. https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/APC-Panel-Archives-Items/CMS1237153. 2.https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices-Items/CMS1204971

How Does this Affect Diagnostic Radiopharmaceuticals?

- Older, high volume radiopharmaceutical drugs are packaged with newer, low volume drugs, resulting in significant underpayment for new technology
- In many instances, the low volume diagnostic radiopharmaceutical itself costs more than two or three times the total reimbursement for the APC

APC	Description	APC 2020 Medicare National Average Reimbursement	APC Offset	Average Cost of Diagnostic Radiopharmaceuticals
5591	Level 1 Nuclear Medicine	$368.08	$51.64	$60-$4,000 per dose
5592	Level 2 Nuclear Medicine	$471.93	$92.40	
5593	Level 3 Nuclear Medicine	$1,272.05	$338.87	
5594	Level 4 Nuclear Medicine	$1,443.00	$269.84	

Source: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index. Accessed 4.16.20.

Congress and CMS Were Aware Packaging Drugs Could Limit Access

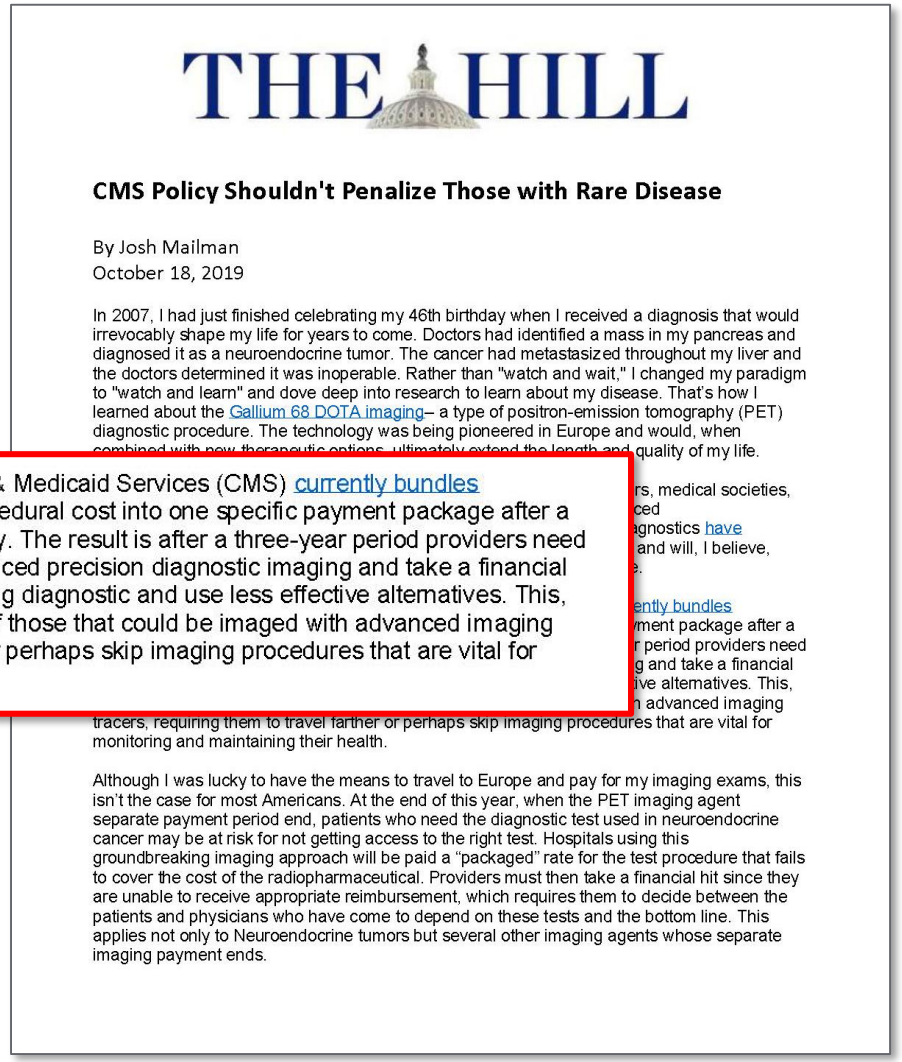
CMS recognizes the adverse effects on access

"*Notwithstanding our commitment to package as many costs as possible, we are aware that packaging payments for certain drugs, biologicals, and* ***radiopharmaceuticals, especially those that are particularly expensive or rarely used, might result in insufficient payments to hospitals, which could adversely affect beneficiary access to medically necessary services."*** 69 Fed. Reg. 50505 (Aug. 16, 2004)

Congress created the "Two Times Rule"

- Ensures cost similarity among procedures in the same APC—the highest cost procedure cannot be more than two times the cost of the least expensive procedures in the APC
  - But CMS refuses to include packaged drugs in its two times calculations

Patients Know, Too…



THE HILL

CMS Policy Shouldn't Penalize Those with Rare Disease

By Josh Mailman
October 18, 2019

In 2007, I had just finished celebrating my 46th birthday when I received a diagnosis that would irrevocably shape my life for years to come. Doctors had identified a mass in my pancreas and diagnosed it as a neuroendocrine tumor. The cancer had metastasized throughout my liver and the doctors determined it was inoperable. Rather than "watch and wait," I changed my paradigm to "watch and learn" and dove deep into research to learn about my disease. That's how I learned about the Gallium 68 DOTA imaging– a type of positron-emission tomography (PET) diagnostic procedure. The technology was being pioneered in Europe and would, when combined with new therapeutic options, ultimately extend the length and quality of my life.

Unfortunately, the Centers for Medicare & Medicaid Services (CMS) currently bundles innovative diagnostic tools and their procedural cost into one specific payment package after a short period of paying for them separately. The result is after a three-year period providers need to make choices about using more advanced precision diagnostic imaging and take a financial loss or stop offering the advanced imaging diagnostic and use less effective alternatives. This, in turn, impacts the diagnosis and care of those that could be imaged with advanced imaging tracers, requiring them to travel farther or perhaps skip imaging procedures that are vital for monitoring and maintaining their health.

Although I was lucky to have the means to travel to Europe and pay for my imaging exams, this isn't the case for most Americans. At the end of this year, when the PET imaging agent separate payment period end, patients who need the diagnostic test used in neuroendocrine cancer may be at risk for not getting access to the right test. Hospitals using this groundbreaking imaging approach will be paid a "packaged" rate for the test procedure that fails to cover the cost of the radiopharmaceutical. Providers must then take a financial hit since they are unable to receive appropriate reimbursement, which requires them to decide between the patients and physicians who have come to depend on these tests and the bottom line. This applies not only to Neuroendocrine tumors but several other imaging agents whose separate imaging payment ends.

Josh Mailman is President of NorCal CarciNET Community and a Board Member of the Neuroendocrine Tumor Research Foundation. He was the Inaugural Chair of the Patient Advocacy Advisory Board for the Society of Nuclear Medicine and continues to be on their Advisory Board.

…And So Do Physicians

"The SNMMI is greatly concerned for our patients as **some hospitals have stopped performing services and they are forced to go elsewhere for their testing**. We are also **concerned for innovation and sustained products** as we have seen companies exit or reduce participation in the Nuclear Medicine Radiopharmaceutical market in recent years."

SNMMI, APC Panel Meeting
HOP Panel Presentation
July 24, 2015

The Solution – Unpackage Diagnostic Radiopharmaceuticals Costing Over $500

CMS must unpackage low-volume, higher-cost radiopharmaceutical diagnostics

- Aligns payment to other drug payment methodology
  - Reimbursement at cost
- Will be budget neutral

Questions?

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