

U.S. Tc-99m Payment Initiative



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OECD Targeted Principles

GOAL: STABLE SUPPLY

- Principle 1: Promote FCR
- Principle 3: Encourage market
 - Consider separating isotope from radiopharmaceutical and diagnostic procedure
- Principle 4: Promote non-HEU
- US Commitment: Examine health insurance payment options to promote sustainable non-HEU supply of Mo-99

U.S. Principles

GOAL: STABLE SUPPLY BASED ON NON-HEU

- Promote Development/Investment
 - FCR
 - DOE Development Initiatives
- Promote non-HEU/Reduce HEU
- Encourage (Protect) Market

CMS Principles

GOAL: STABLE SUPPLY (Population) of Diagnostic Tests (Patient) at Affordable Cost (Cost)



- Reimbursement (vs. Incentive)
 - Incentive: a “bonus” to create new behavior
 - Reimbursement: compensation for existing behavior

Initiative Goals and Constraints

- Create a payment to *cover increased costs* of *Medicare portion* of FCR and non-HEU sources
- Create a signal that Medicare backs sustainable pricing
- Create a model for use by other payers
- Must be consistent with statutory authority
- Must be acceptable to healthcare industry
- Should be simple and transferable to other payers
- Must = reimbursement

The Problem

- Unbundling Radiopharmaceutical does not create payment offset for Non-HEU/FCR
- Unbundling Radioisotope does not create payment offset for Non-HEU/FCR
- Unbundling is not consistent with CMS reimbursement models to increase hospital and physician choice
- CMS can pay costs NOT incentive
- FCR is not easily audited or tracked

The Solution

- Non-HEU sourced production is newer and more consistently based on FCR
- Non-HEU sourcing is more easily tracked and audited
- Non-HEU sourcing creates an artificial benefit as a proxy for FCR (co-attribute)
- Unbundling of the attribute creates a defined and visible payment differential *but* only the industry can ensure that the added payment is passed back to the reactor and processor

The Payment: Q9969

- CMS created a new payment effective 1/1/2013 to cover the added cost of producing Tc-99m from non-HEU sources using Full Cost Recovery
- This is a \$10 per dose add-on payment by Medicare for all hospital outpatient Tc-99m tests
 - As a practical matter, the inpatient payment system does not support small added payments.
 - The legal authority for the payment does not extend to physician offices.
 - Many Medicaid and commercial programs follow CMS practices in paying claims

The Impact

- The payment could allow a radiopharmacy to absorb a doubling of generator cost
- Total payment will (initially) be less than maximum because all payers will not accept coding
- Important signal that Medicare is absorbing added cost is already triggering market changes to increase non-HEU/FCR supply
- The function of the payment is to reimburse additional production cost (non-HEU and FCR) not to create incentives within the supply chain

Economic Analysis

- The CMS model is a supply chain model
 - Mo-99 activity is traced from producer to generator
 - Tc-99 activity is traced from generator to patient
- Efficiency (C_i out per C_i in) is traced through each step
 - Activity lost to decay is differentiated from activity lost due to process
- Generator efficiency is based on elution pattern
- Process model tracks doses per week Tc-99m as a function of C_i Mo-99 per week produced

Major Conclusions

- **The industry has not disclosed any information to suggest a significant deviation from the range of the OECD models**
- The model does not suggest a high likelihood of a non-competitive *product* (dose) using Non-HEU sources at FCR, consistent with the current introduction of non-HEU sources
- A competitive advantage of subsidized HEU production can exist in the early steps in the supply chain, but is not reduced by increasing prices/revenue of the (undifferentiated) Tc-99m dose
- Modest increases in payments will cover increased Mo-99 costs, but there is no guarantee and in fact little economic pressure to ensure that increased payments will flow back to producers and processors
- **Payment initiatives cannot promote FCR; they can only support an industry-wide movement to FCR**

Payment Initiatives Cannot Support FCR in the US Market

- Since there is no difference in benefit between FCR doses and subsidized doses, market reforms depend on equalizing user costs (taxes, subsidies, pass through payments)
- Cost differential is at the reactor (and processor) level, so cost equalizing initiative must be passed through (unbundled)
- Payment differential does not pass through the generator/extraction steps because there is not a 1:1 correspondence between Ci Mo-99 and Ci Tc-99m

Questions?

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