UPPI LEU Walk: Implementation Strategy on the Verge of a Supply Chain Converted to non-HEU Medical Isotopes

2017 Mo-99 Topical Meeting on Molybdenum-99 Production Technology Development

September 10-13, 2017
Montreal Marriott Chateau Champlain
Montreal, QC Canada
Agenda

- UPPI LEU Walk
- Vizient – UPPI white paper
- ASP and Private Payer C-Suite Initiatives
- Review of FOIA data from the Veterans Administration
- Summary
Overview UPPI LLC.

• UPPI is an alliance of small business and university owned nuclear pharmacies.
• Formed in 1998, with low energy and high energy nuclear pharmacies.
• UPPI represents 8,000 of the 50,000 unit doses dispensed every day in the U.S.
UPPI LEU Walk Progress: 2013 - Today

Three UPPI LEU Pharmacies
Figure 3. Successfully transitioning to an HEU-free medical isotope supply involves many stakeholders.

- Hospital supply chain
- Domestic supply
- Full cost recovery

- CMS reimbursement
- GPO stakeholders
- Managed care organization reimbursement

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Abbreviations: CMS, Centers for Medicare & Medicaid Services; GPO, group purchasing organization; HEU, highly-enriched uranium.*
ASP Reimbursement Outreach
Radiopharmaceuticals need classification as physician injected drug based on ASP.

**Trendline will sharply rise when FCR and ORC for Tc 99m moves through the supply chain.**
C-Suite LEU Tc 99m
Reimbursement Outreach
### Lean Canvas Business Model

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<th>Problems</th>
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<th>Unique Value Proposition</th>
<th>Unfair Advantage</th>
<th>Customer Segment</th>
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<td>Price -Full Cost Recovery</td>
<td>LEU Policy Program</td>
<td>Transition now</td>
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<td>Transition timing</td>
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<td>Reimbursement Clarity</td>
<td>Early Adopter Map</td>
<td>UPPI First-in/innovator</td>
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<td>Group Purchasing Organization</td>
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<tr>
<th>Key metrics</th>
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| Early Adopter Map | Early Majority Map

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<th>Channels</th>
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<td>Supply Chain</td>
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<td>Radiology Administrators</td>
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<th>Revenue Streams</th>
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<td>All insured lives covered by private payers -reimbursement</td>
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<th>Cost Structure</th>
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<td>GPO contracts</td>
<td>AMIPA</td>
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<td>Manage price increases</td>
<td>Transition now</td>
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### C-Suite Initiative:

A **patient –centric non-proliferation policy** to remove Highly Enriched Uranium from medical isotopes production.
C-suite Non-proliferation Outreach

Which Patient is Eligible for CMS HOPPS non-HEU Medical Isotopes Reimbursement?

C-Suite Initiative:
A patient-centric non-proliferation policy to remove Highly Enriched Uranium from medical isotopes production through coverage of all insured lives.

Solution: Establish the Q9969 policy for all covered lives who receive non-HEU Tc99m diagnostic imaging study.

C-Suite Initiative:
A patient-centric non-proliferation policy to remove Highly Enriched Uranium from medical isotopes production through coverage of all insured lives.

Medicare HOPPS receives the $10.00 Q9969 added reimbursement. If one of nine is eligible then how does a busy department separate the one for reimbursement? For $10.00? It's easier to add another study...
Why the Need for the Reimbursement Support?

The elimination of Highly Enriched Uranium is a policy of governments. To convert to the non-HEU solution is more expensive with the increased costs due to government policies.

Sustainability of the supply is a result of the costs—not driven by profit—and reimbursement is a key factor to sustainability.

Private payers play essential role in the transition to non-HEU (LEU) medical isotopes.
Private Payer Outreach

- Why not provide the Qcode coverage for a boy with a sarcoma needing a bone scan?
- Why not provide the Qcode coverage middle-aged patient with a GI bleed?

https://radiopaedia.org/cases/osteosarcoma-of-the-distal-femur

$26.00 per dose
Q9969 non-HEU 99mTc - Private Payer/Medicaid

Private Payer Targets

Chief Medical/Clinical...
Chief Executive Officer
Provider Contracting
Pharmacy Director
Chief Operations...
Claims Management
Chief Marketing/Sales...
Public Relations
Government Relations
Medicare Operations
Disease...
President

New Hampshire Healthy Families
New Hampshire Medicaid
Fallon Community Health Plan
Carilion Clinic Medicare Health Plan
Virginia Medicaid
Aetna
AvMed
BC/BS of Florida
Humana (In-Humana)
United Health Care
Magnolia Health Plan
Mississippi Medicaid
Arkansas Medicaid
BCBS Arkansas
Arkansas Medicaid
Louisiana Health Connect
Home State Health Plan Missouri
Buckeye Health Plan
Illinicare Health Plan Illinois
Minnesota Medicaid
New Mexico Medicaid
Utah Medicaid
Maine Medicare – Wyoming Medicaid

UPPI National Academies of Science Presentation November 3, 2015
Facilitating the Availability of Safe Nuclear Medicine: 
Reducing the Dependence on Highly Enriched Uranium

“Highly enriched uranium (HEU)—one of the key ingredients for nuclear weapons—is one of the most dangerous materials on the planet.”
-The Nuclear Threat Initiative

Problem: The use of HEU is still too prevalent in U.S. medical procedures even though LEU is broadly available and could serve as an easy substitute to HEU.

Every year in the US, more than 15 million medical tests are performed using enriched uranium byproducts—more than 41,000 procedures per day. These tests are used to diagnose and assess cancer treatment effectiveness, detect heart disease and other disease processes.

Over 78% of these procedures use Highly Enriched Uranium (HEU), which has been called “one of the most dangerous materials on the planet” by the Nuclear Threat Initiative because it is relatively easy for terrorists or others use that material to make a simple nuclear bomb.

LEU, which does not present the same risk, is an approved substitute that could be used instead of HEU.

There has been a long-term effort to substitute the use of LEU for HEU in U.S. medical
Veterans Affairs non-HEU
Tc 99m
UPPI Freedom of Information Request

- How many VA facilities receive LEU Tc $^{99}$m doses?
- What is the verification process/procedure that ensures doses are indeed LEU when awarded on a solicitation?
- Regarding the contracting process, if non-HEU (LEU) is required by the agency and is written into the solicitation by the Contracting Officer, under what conditions is it not procured? What inquiries are made in option years to determine if LEU is available?
- Provide copies of all communications related to the notifications, and any training, materials, communications or other material related to that notification.
UPPI FOIA Request

VHA Non-HEU Tc-99m Estimated Dose Cost (FY 2012)

10/1/2012 through 9/30/2013

Cost to transition to non-HEU

VAMC Dose Costs  Estimated Incremental Cost  Mean  +1 SD
VHA Non-HEU Tc-99m Estimated Dose Cost (FY 2012)

Non-HEU sites reported by the VA (5)
VHA Non-HEU Tc-99m Estimated Dose Cost (FY 2012)

Actual Non-HEU sites (27)
These facilities awarded LEU Tc 99m doses in 2015. Neither ordered a single LEU dose and used HEU product instead.
VA Solicitation in July 2017

Statement of Work: Background

The Department of Veterans Affairs (VA) has been directed to preferentially procure medical radioisotopes from non-High Enriched Uranium (HEU) sources.

Contract Line Item Number specified HEU:

- Exametazime (Ceretec) Brain Tc-99m HEU
- Exametazime (Ceretec) WBC Tc-99m HEU
- Mebrofenin (Generic) Tc-99m HEU
- Medronate (MDP) Tc-99m HEU
- Mertiatide (MAG-3) Tc-99m HEU
- Oxidronate (HDP) Tc-99m HEU
- Pentetate (DTPA) Tc-99m HEU
- Pentetate (DTPA) Tc-99m HEU, Bulk
Conclusion of the FOIA Information

- Of 117 RAM licensed facilities, <25% converted to non-HEU
- Estimated non-HEU dose cost analysis in 2013
- Two memoranda regarding preferential procurement
- De minimus response to questions
- Clinical group received preferential procurement notices
- Contracts group did not receive notices – contract officers are the warrant holders for the bid solicitations and specifications.
Summary
Sustaining the Transition to non-HEU Medical Isotopes

• Initiatives:
  – Change reimbursement to an ASP model to sustain nuclear medicine.
  – C-Suite outreach to private payers to drive adequate non-HEU reimbursement through 2020.
  – Work-with the Veterans Administration to understand its non-HEU transition.
KEEP CALM WITH LEU AND CARRY ON