Radiopharmaceutical Reimbursement PBS Guide

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Accurate management and monitoring of radiopharmaceutical reimbursement are essential due to the significant costs involved for radiology practices. Clinical progress and FDA approval of numerous new PET radiopharmaceuticals have driven many practices to invest in additional drugs and testing protocols. Examples include:

- PSMA agents such as piflufolastat F-18 (Pylarify®, A9595) and Ga-68 gozetide (Illuccix®, A9596) for prostate cancer imaging
- Fluciclovine F-18 (Axumin®, A9588) for recurrent prostate cancer
- Amyloid tracers such as florbetapir F-18 (Amyvid®, A9586) for Alzheimer's disease evaluation
- Other novel PET agents in neurology, oncology, and cardiology

With expanding availability and increasing utilization of these high-cost agents, correct billing and reimbursement practices are critical for financial sustainability. Below, we outline essential considerations and best practices.

Per Study Dose

Radiopharmaceuticals for diagnostic purposes are often billed using codes defined as "per study dose." These codes typically specify an "up to" amount. For example, HCPCS code A9538 states: Technetium Tc-99m pyrophosphate, diagnostic, per study dose, up to 25 mCi.

The Society of Nuclear Medicine and Molecular Imaging (SNMMI) clarifies that the "up-to-dose" definition refers to the maximum radiopharmaceutical quantity administered to a patient for a single imaging study. CMS generally uses the manufacturer's package insert maximum dose as the upper limit.

1. Bill one study dose per imaging session, even if multiple syringes or containers are used or the dose exceeds the "up to" amount.
2. If a patient undergoes rest and stress imaging in separate injections, bill as two study doses, unless the payer instructs otherwise.
3. Be aware that not all radiopharmaceuticals are billed per study dose. For example, A9596 (Ga-68 gozetide, Illuccix®) is billed per mCi. In these cases, the administered amount (plus any wastage) must be documented and billed accurately to match the HCPCS unit definition.

Radiopharmaceutical Waste

Because many radiopharmaceuticals are supplied in single-use vials, some portion may remain unused after patient dosing. CMS requires providers to account for this wastage on claims:

Modifier JW

Must be reported for any discarded amount of a single-use vial that was not administered. This modifier is billed on a separate claim line for the wasted portion.

Modifier JZ

Must be reported when no drug was discarded, confirming that the full vial was administered.

Accurate wastage reporting is important for compliance and reimbursement integrity. Facilities should ensure their documentation reflects the amount administered versus the amount discarded.

Assay Amount

Prior to administration, radiopharmaceutical doses are assayed for radioactivity levels. Minor variances between the ordered dose and the assayed dose are expected. Billing, however, should reflect the ordered dose, not the assay amount. Claims must align with purchase invoice quantities to avoid denial.

Missed Appointments

If a patient misses an appointment and the radiopharmaceutical was never administered, Medicare does not allow billing for either the drug or wastage. SNMMI emphasizes that patient no-shows do not create a billable event.

However, CMS permits practices to charge patients directly for missed appointments, provided the policy is applied consistently across all patients and payers. Such charges should not be billed to Medicare. Some practices ask patients to sign acknowledgment forms regarding cancellation policies. Always consult legal counsel before implementing such measures to comply with state law.

If a patient receives the radiopharmaceutical but does not return for the full imaging series:

- Bill for the partial study and the radiopharmaceutical administered.
- If no imaging occurred, bill the intended study code with modifier 52 (Reduced services).
- Modifier 52 applies only to the imaging study, not the drug itself.
- Ensure the radiologist documents ordered studies, drug administration, and follow-up attempts.

Payer Billing Requirements

Many payers limit reimbursement for radiopharmaceuticals to the facility's acquisition cost. Policies may require reporting the invoice cost directly on the claim or submitting the invoice upon request.

Example: Novitas Medicare requires acquisition cost reporting in Block 19 or Block 24D of the CMS 1500 form (or electronic equivalent). Claims without this detail may be denied.

When reporting costs, be sure to:

- Include shipping and handling charges, as they are considered legitimate procurement expenses.
- Maintain clear invoice documentation for audit readiness.

Imaging-Related Drugs

Medicare Part B reimburses many drugs, including radiopharmaceuticals, based on the Average Sales Price (ASP) methodology. Manufacturers report sales prices quarterly, and CMS adjusts reimbursement rates for the following quarter.

For updated reimbursement information, see the CMS Part B ASP resource page (link below).

Our Monitoring and Management Program

Our team provides detailed oversight to safeguard appropriate reimbursement for radiopharmaceuticals. Our program includes:

Monitoring

Close monitoring of high-dollar radiopharmaceutical claims

Auditing

Regular coding audits to ensure accurate billing

Follow-up

Proactive claims monitoring and follow-up on discrepancies

Review

Ongoing review of payer adherence to reimbursement guidelines, including for newly approved drugs

Our program also includes contract addendum support and renegotiation when underpayment patterns are identified, profit and loss tracking with monthly leadership reporting, and strategic recommendations for pricing and payer negotiations.

Key Resources

- SNMMI Coding and Reimbursement Resources: **https://www.snmmi.org**
- CMS Medicare Claims Processing Manual (Chapter 1, Section 30.3.13): **https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c01.pdf**
- Medicare Part B Drug Average Sales Price: **https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price**

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