

Medicare Coverage and Quantitative Imaging Biomarkers

Office of Clinical Standards and Quality
Centers for Medicare & Medicaid Services
Department of Health and Human Services

There can be no doubt but that the statutes and provisions in question, involving the financing of Medicare and Medicaid, are among the most completely impenetrable texts within human experience. Indeed, one approaches them at the level of specificity herein demanded with dread, for not only are they dense reading of the most tortuous kind, but Congress also revisits the area frequently, generously cutting and pruning in the process and making any solid grasp of the matters addressed merely a passing phase.

Rehabilitation Association of Virginia, Inc. v. Kozlowski, et al., 42 F. 3d 1444,1450 (4th Cir. 1994)

Social Security Act 1862(a)(1)(A)

R & N

“...no payment may be made...for items or services – which ... are not

reasonable and necessary

for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

Reasonable and Necessary

Adequate evidence to conclude that the item or service improves clinically meaningful health outcomes for the Medicare population

42 CFR 410.32(a)

“All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests **must be ordered by the physician who is treating the beneficiary**, that is, the physician who furnishes a consultation or treats a beneficiary for a **specific medical problem and who uses the results in the management of the beneficiary’s specific medical problem...**”

Health Outcomes

More Impressive

- ▶ Longer life and improved function/participation
- ▶ Longer life with arrested decline
- ▶ Significant symptom improvement allowing better function/participation
- ▶ Reduced need for burdensome tests and treatments

Less Impressive

- ▶ Longer life with declining function/participation
- ▶ Improved disease-specific survival without improved overall survival
- ▶ Surrogate test result better
- ▶ Image looks better
- ▶ Doctor feels confident

Better evidence...

- ▶ is biologically plausible; and
- ▶ is internally consistent; and
- ▶ demonstrates a durable effect; and
- ▶ minimizes bias and confounding; and
- ▶ is generalizable to Medicare beneficiaries.

Why not rely solely on doctors and experts?

- ▶ Assessing effectiveness through intuition has proven unreliable
- ▶ Data shows imperfect practice
 - wide geographic variations
 - high rates of inappropriate care
 - medical errors
- ▶ Factors other than clinical may influence

The Preferred Road to Diagnostic Coverage

- ✓ Provide adequate evidence that
- ✓ The incremental information obtained by new diagnostic technology compared to alternatives
- ✓ Changes physician recommendations
- ✓ Resulting in changes in therapy
- ✓ That improve clinically meaningful health outcomes
- ✓ In Medicare beneficiaries

“Men stumble over the truth from time to time, but most pick themselves up and hurry off as if nothing had happened...”

–W. Churchill