KING & SPALDING LLP

Ace Left Brain Stimulation Device

Strategy for Medicare Coverage and Payment

Michael J. Ruggiero
King & Spalding LLP
202-661-7866
mruggiero@kslaw.com

KING & SPALDING LLP

I. Preparation and Analysis

Preparation and Analysis

- Researched Coverage, Coding, and Payment Environment
  - Comparable technologies
  - Existing coverage policies
  - Existing codes
  - Existing payment rules
  - Timelines for coding and payment rules

Preparation and Analysis

- Identified "Key Opinion Leaders"
  - Clinical investigators, authors of peer-reviewed articles, key leaders of relevant specialty societies
    - AAN, AANS
  - Role will be communicating with regulators and others about importance and clinical benefits of technology
- Assembled Coalition
  - Key medical specialty societies
  - Patient groups

Preparation and Analysis

- Collected Relevant Clinical Literature
  - Build best scientific case for coverage of technology
    - Improved function/mobility in stroke patients treated with device
    - Fewer complications than traditional therapies
    - Fewer side effects
  - US and Medicare-age clinical data most relevant
- Performed Cost Analysis for Device and Procedure (Outside Entity)

Preparation and Analysis

- Prepared "White Paper"
  - Polished summary/advocacy paper outlining clinical/scientific data and supporting case for coverage
  - Audience primarily regulators/advisory panel; potentially other stakeholders
- Did Not Hold Preliminary Meetings with CMS
  - Coverage/payment staff
  - Explain technology / clinical benefits
  - Solicit questions and concerns

KING & SPALDING LLP

II. Coverage

Coverage

- Existing Coverage Policy
  - National Coverage Decision covered deep brain stimulation for Parkinson's & Essential Tremor under certain circumstances
  - But deep brain stimulation non-covered for "motor function disorders"
- Ambiguous
  - Is stroke nationally non-covered?
  - Or left to contractor discretion?

Coverage

- First (Preferred) Strategy: Local Coverage Approach
  - Informal discussions with a few contractors indicated some concerns about paying in light of NCD
  - Met with CMS
    - CMS took position that stroke indication was non-covered

Coverage

- Second Strategy: National Coverage Approach
  - Worked with stakeholders to petition CMS to revise NCD
  - Submitted formal application for expansion of NCD
    - Drawn largely from White Paper/clinical data prepared and gathered during preparations

Coverage

- CMS Convened Medicare Coverage Advisory Committee (MCAC)
  - Panel of 15 experts (selected from committee of 100) from various disciplines charged with evaluating evidence and making coverage recommendations to Medicare
- Requested AHRQ Technology Assessment
  - Duke EPC
    - Found compelling evidence for clinical benefits, but lack of large prospective randomized trials focusing on Medicare-age population.

Coverage

- MCAC (cont.)
  - Chose KOLs to present evidence
  - Worked with internal clinical, physicians to prepare presentation
  - Negotiated with CMS over agenda and questions to be considered
    - Secured time for stroke patient representative to provide first-hand account of benefits / restored function

Coverage

- Favorable MCAC Recommendation . . .
  - Question: "How confident are you that deep brain stimulation will produce a clinically important net health benefit in restoring motor function in stroke patients who have not responded to other treatments"?
  - Score: 4.2 / 5.0

Coverage

- . . . But not as strong as we would have liked
  - Question: "Based on the literature presented, how likely is it that the results of deep brain stimulation in the treatment of motor function loss due to stroke can be generalized to the Medicare population (aged 65+)"?
  - Score: 3.0 / 5.0

Coverage

- CMS Expands Coverage
  - Revised NCD issued that includes stroke-induced motor function loss as covered indication for deep brain stimulation under certain circumstances
- Coverage with Evidence Development
  - Lack of robust data for Medicare-aged population
  - Negotiation with agency resulted in registry enrollment as condition of coverage

KING & SPALDING LLP

III. Physician Coding and Payment

Physician Coding & Payment

- Covered by existing codes
  - CPT 61863 / 67
    - implantation of neurostimulator electrode array in subcortical site, without / with use of microelectrode recording device
    - $1,371 / $2,076 payment
  - CPT 61885
    - implantation of cranial neurostimulator pulse generator with connection to single array
    - $483 payment

KING & SPALDING LLP

IV. Inpatient Coding and Payment

Inpatient Coding & Payment

- Insertion of lead always inpatient procedure
- Implantation of pulse generator may be inpatient procedure

- Need inpatient coding & payment for both

Inpatient Coding & Payment

- Good News: Coding Exists
  - Lead placement -- ICD-9 02.93
    - implantation of intracranial neurostransmitter lead
  - Pulse generator placement -- ICD-9 86.94
    - implantation of single array pulse generator

Inpatient Coding & Payment

- Bad News: Inadequate Payment
  - $ 24,000 cost of procedure ($16,000 device)
  - $ 5,894 payment (DRG 14 -- stroke)

    or
  - $ 16,251 payment (DRG 1 - craniotomy with complications/co-morbidities)
  - $ 9,267 payment (DRG 2 - craniotomy without complications/co-morbidities)

– Options:

1. New-technology add-on payment (difficult)
2. New DRG (very difficult)

Inpatient Coding & Payment

- Secured New-Tech Add-On Payment
  - "New" (within 2-3 years of FDA approval)
  - Clinical benefit
    - Data show strong clinical benefit for restored function/reduced complications and side effects in stroke patients who failed other treatment options
  - Cost
    - Case-weighted charges: $49,000
    - DRG 1-2 cost threshold: $35,000
  - Additional payment of up to $8,000
- Total payment: $24,251 / $17,267

KING & SPALDING LLP

V. Outpatient Coding and Payment

Outpatient Coding & Payment

- Placement of pulse generator usually outpatient
- Existing codes
  - CPT 61885
    - implantation of cranial neurostimulator pulse generator with connection to single array
  - APC 039
    - Level I Implantation of Neurostimulator
    - $11,602

Outpatient Coding & Payment

- Explored OPPS new-technology options
  - New technology procedure APC assignment
    - Procedure deemed similar to implantation of other pulse generators
  - New technology device pass-through payment
    - Device deemed similar to existing pulse generators

KING & SPALDING LLP

End

KING & SPALDING LLP

Medicare Secondary Payer Act: CMS Recovery from Ace

Medicare Secondary Payer Issues

- Under PPS, generally no payment adjustment to reflect devices obtained free of charge (*e.g.*, pursuant to warranty)
- Medicare Benefit Policy Manual:
  - "When . . . a defective medical device is replaced under a warranty, hospital or other provider services rendered by parties other than the warrantor are covered despite the warrantor's liability. However, see the Medicare MSP Manual . . . for requirements for recovery under the liability insurance provisions."

Medicare Secondary Payer Issues

Medicare Secondary Payer Statute ("MSP")

- Generally makes Medicare the "secondary payer" for healthcare services where another "plan" is "responsible"
  - Applies with respect to private health plans, workers' compensation programs, and "liability insurance," including those that are "self-insured plans"

Medicare Secondary Payer Issues

How the MSP operates:

- Generally precludes Medicare payment where payment can be made by another "plan"
- But, permits "conditional payments," subject to recovery once "responsibility" of a plan is "demonstrated"
  - Statute provides for recovery by private plaintiffs*

Medicare Secondary Payer Issues

History:

- Plaintiffs (and Federal Government) sought to recover from tobacco manufacturers / tortfeasors as "self-insured" liability insurance
  - Sought healthcare expenses incurred to treat smoking-related illnesses in Medicare beneficiaries
  - Argued tobacco companies had become "self-insured plans" by failing to purchase insurance

Medicare Secondary Payer Issues

History (cont.):

- Federal courts (esp. Goetzman) rejected approach, holding that:
  - Congress did not intend "self-insured plans" to include companies not engaged in business of providing insurance
  - Cannot become a "plan" merely by carrying own risk of liability (*e.g.,* failing to purchase insurance)

Medicare Secondary Payer Issues

Medicare Modernization Act:

- Amended MSP to provide that:
  - "Self-insured plans" could encompass non-insurance businesses
  - Recovery of conditional payments by Medicare requires "demonstration" of a plan's "responsibility" to make payment
    - "Responsibility" can be demonstrated by "judgment, settlement, or other means"

Medicare Secondary Payer Issues

Meaning of MMA Amendments:

- Indicate that legal responsibility must be demonstrated for Medicare to recover
- MSP regulations (amended by Interim Final Rule 2/24/06) follow this approach:
  - "Responsibility" may be demonstrated by a judgment, a payment conditioned on the recipient's compromise, waiver, or release, or "by other means, including but not limited to a settlement, award, or contractual obligation."

Medicare Secondary Payer Issues

Back to Ace Recall:

- Possible to become a "plan" under the MSP
- But, recovery not permitted from Ace until legal responsibility for payment is demonstrated
  - Judgment, settlement, contract

Medicare Secondary Payer Issues

- Process of Recovery:
  - COB contractor responsible for identifying potential claims
  - Notifies beneficiaries, plaintiffs' counsel, and manufacturer of Medicare right of recovery in case of judgment or settlement
  - Recovery permitted from "plan" or beneficiary, regardless of whether plan already made payment to beneficiary
  - Double damages available from plans that fail to make required payment

KING & SPALDING LLP

End

Michael J. Ruggiero
King & Spalding LLP
202-661-7866
mruggiero@kslaw.com