Disclaimer

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Over 140 million Americans receive healthcare coverage through programs administered by CMS.

- **Medicare**: Health insurance for individuals age 65 and older, as well as those with disabilities.
- **Medicaid/CHIP**: Health insurance managed by the states for individuals with lower incomes.
- **Health Insurance Marketplaces**: A resource that allows individuals to sign-up for private health insurance with tax credits to offset premiums.

Over 140 million Americans receive healthcare coverage through programs administered by CMS.
CMS: 6 Policy Centers

Center for Medicare (FFS and MA)

Center for Medicaid and CHIP Services

Center for Clinical Standards and Quality

Center for Medicare and Medicaid Innovation

Center for Consumer Information and Insurance Oversight

Center for Program Integrity
Center for Clinical Standards & Quality

- Over 500 federal FTEs, $2 billion in budget, and approximately 10K contractors focused on improving quality across the nation
- Leadership at CMS in Continuous Improvement and transformation of IT system development
- Contemporary Quality Improvement: Quality Improvement Networks and QI initiatives for all provider types
- Quality Measurement and Public Reporting: Outcome, patient experience & cost measures, IMPACT Act, Star ratings
- Incentives: Quality Payment Program, Hospital Value Based Purchasing, ESRD QIP
- Regulation: Conditions of Participation (Hospitals, NH, other provider types) and Quality and Safety Oversight/Enforcement
- Coverage Decisions: coverage with evidence development, medical technology innovation, work with FDA and NIH
- Clinician Engagement: Restoring the clinician/patient relationship
EVIDENCE is Our Primary Focus

- Systematic reviews (Level 1)
- Randomized controlled trials (Level 2)
- Cohort studies (Level 2)
- Case-control studies (Level 3)
- Case-series, case reports (Level 4)
- Expert opinion (Level 5)
Coverage Planning and Approaches

- The majority of companies evaluate coding and payment at the beginning of the product lifecycle.
- For initial meetings on coverage, respondents reported approaching either CMS or both MACs and CMS, never just MACs.
- A minority of companies have gone through the NCD process. Those that did reported the process was time and labor intensive, but the success rates were high.
CMS National Coverage Meetings

88% found meetings with the Coverage & Analysis Group helpful

Value of the input received from these meeting(s) on:

- Understanding evidentiary requirements: High
- Understanding coverage process and timelines: Moderate
- Product design: Low
- Clinical trial design: High
- Evidence development planning: N/A
MDIC Survey

- Lag between CMS coverage, coding and payment
- Patient preference not considered
- Value frameworks not established for end points
- Lag between FDA approval/clearance and CMS coverage
What else we have heard

Lack of Transparency
  • Process is hard to navigate/understand
  • Do not know who to talk with

Lack of Predictability
  • Evidence Standards
  • Local Coverage Determinations
Medicare Coverage Road Map

for FDA Reviewed Technologies

Identify your coverage path

Legend:
- FDA Review Point
- CMS Review Point
- CMS Milestone

IDE = Investigational Device Exemption
CED = Coverage with Evidence Development
NCD = National Coverage Determination
LCD = Local Coverage Determination

Medicare Coverage Road Map
Local Coverage Determinations

Local Coverage Determination Process: Updated with goals of:

- More transparency
- More stakeholder engagement

LCD process changes:

- Requiring a summary of the clinical evidence supporting LCD decisions.
- Including a beneficiary representative and other healthcare professionals in addition to physicians (e.g. nurses, social workers) on Contactor Advisory Committees that inform LCDs.
- Ensuring that Contractor Advisory Committee meetings are open to the public
- Public input Opportunities: 45-day public comment period/Open Meetings
TELL US MORE
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