Improving Evidence in Geriatric Oncology Trials: A Role for Payers?

FDA-ASCO Geriatric Oncology Workshop
November 6, 2017
The question

- Are there ways coverage and reimbursement policy can incentivize design of oncology trials more representative of actual use populations?
- I.e. how do we create leverage or pull from the post-market side to influences choices that take place in pre-market?
  - Coverage with Evidence Development (CED)?
  - Value-based insurance design (VBID)?
  - Other post-market decision-makers and tools?
Background: Payers and Target Populations

• Target population is geriatric
• Payer focus: Medicare (people aged >65 years and not working)
  o Traditional Medicare (parts A and B – hospital/inpatient and medical/physician services, outpatient, lab tests/x-ray, etc.) (many cancer drugs part B)
  o Medicare Advantage plans provided through private insurers
    ▪ parts A&B minimum, plus additional features, benefits
    ▪ Can include Part D
  o Medicare Part D – prescription drugs (self-administered)
CED

• In Medicare, takes place as part of National Coverage Determination for a drug, diagnostic, or device
  o Often response to requests for coverage when “the expectations of interested parties are disproportionate to the existing evidence base.”
  o For “…technologies that are likely to show benefit for the Medicare population, but . . . the available evidence base does not provide a sufficiently persuasive basis for coverage outside the context of a clinical study”
  o Medicare covers product or procedure only in context of well designed clinical trial/registry to fill evidence gaps.

• Useful assist for not-covered, promising technologies…to bring over CMS threshold for evidence

Will CED Change Trial Designs?

• CED applies only to Medicare Part A and B
  o Not self-administered prescription drugs (Part D)
• CED relatively infrequent (23 cases since 2005 – most not drugs)
• Circumstances to justify are fairly specific…
  o Cancer drugs typically covered as a matter of policy
  o Would younger-skewed study population constitute “evidence . . . insufficient to support coverage outside the context of a well-designed clinical research study”?
• In some cases may be useful to promote phase 4 studies, but unlikely to impact design of phase 2 & 3 studies
VBID a better opportunity?

- Value-Based Insurance Design (VBID)
- Use plan design to ‘nudge’ behavior of enrollees
- Encourage plan enrollees to consume high-value clinical services
  - More or less copays
- Effective Jan 2017 CMS (CMMI) piloting VBID in Medicare Advantage Plans in 7 States
- Currently limited to certain chronic conditions
What if Medicare...?

- Included Oncology Drugs in VBID Pilot Medicare Advantage
  - And prioritized drugs with evidence of benefit in older pops
    - And reduced coinsurance for enrollees opting for these drugs?
    - Or required step therapy (drug with benefit shown in older pop must be tried first)?
    - Or higher reimburse for products w/ real-world benefit, lower toxicity, in older pop?
      (Outcomes-based reimbursement)

(Preauthorization)
Other opportunities

- Value frameworks for oncology drugs
  - ASCO
  - MSKCC
  - ICER
  - Others

- Clinical practice guidelines
  - ASCO
  - NCCN

- Include in definition of “value” evidence of benefit in population representative of people to be treated

- Esp. if “value” linked to price

- Downgrade level of evidence, or somehow flag, if supporting evidence population skewed significantly younger
Make Consensus Recommendations

• Convene payers, guideline developers, creators of value frameworks, and other influential “post-regulatory” decision-makers

• Establish consensus of these groups on “desirable” study designs w/representativeness of patient population as criterion

• Agree that “desirable” study features could affect…
  o Value framework / evidence assessment
  o Formulary tier
  o Reimbursement and patient cost-sharing
  o Other aspects of benefit design

• Can have pull to affect drug development trial design choices