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

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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)
  - Traditional Medicare (parts A and B – hospital/inpatient and medical/physician services, outpatient, lab tests/x-ray, etc.) (many cancer drugs part B)
  - Medicare Advantage plans provided through private insurers
    - parts A&B minimum, plus additional features, benefits
    - Can include Part D
  - Medicare Part D – prescription drugs (self-administered)

CED

- In Medicare, takes place as part of National Coverage Determination for a drug, diagnostic, or device
  - Often response to requests for coverage when “the expectations of interested parties are disproportionate to the existing evidence base.”
  - 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”
  - 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

https://www.cms.gov/medicare-coverage-database/details/medicare-coverage-document-details.aspx?MCDId=27

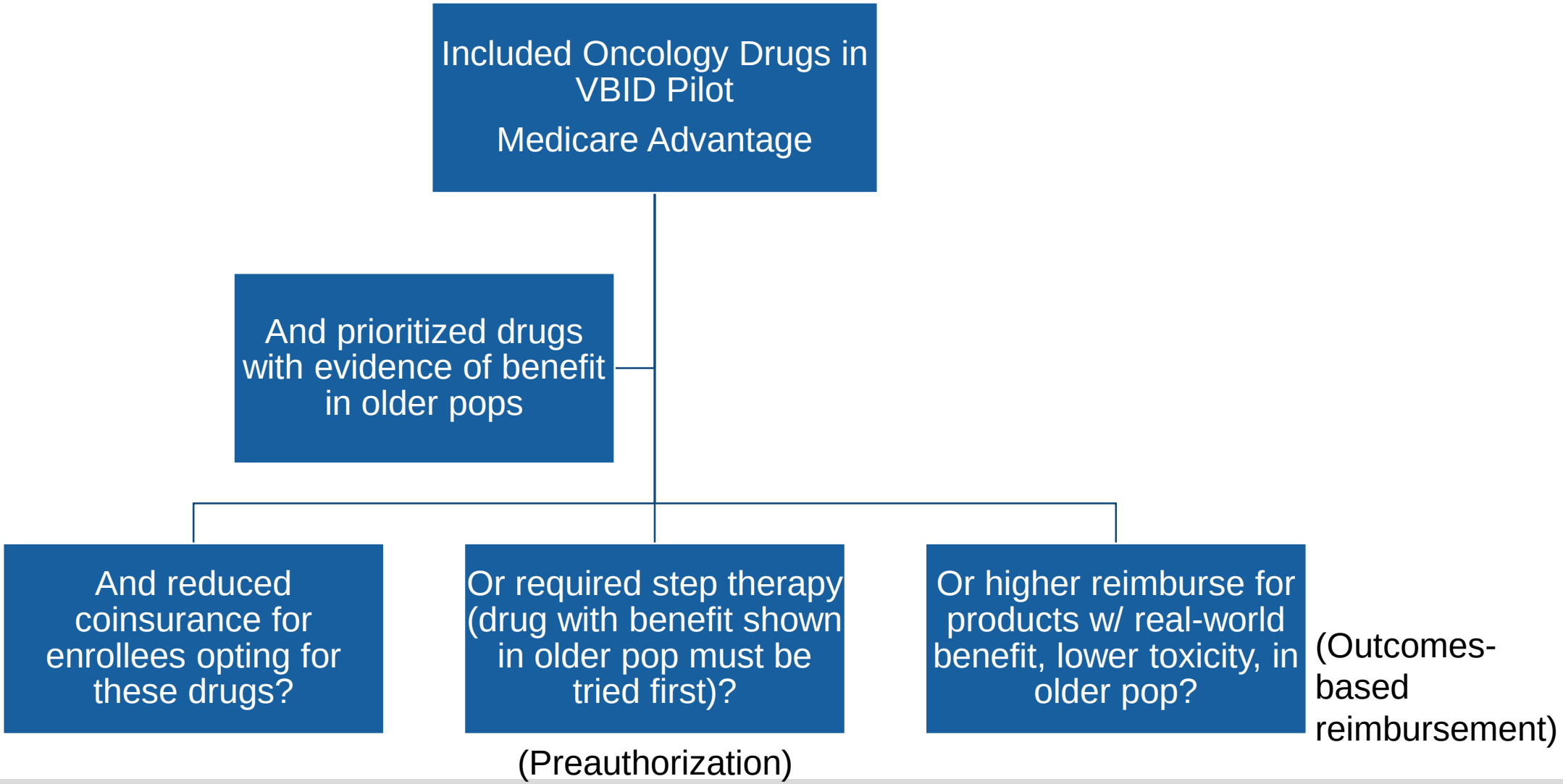
Will CED Change Trial Designs?

- CED applies only to Medicare Part A and B
  - Not self-administered prescription drugs (Part D)
- CED relatively infrequent (23 cases since 2005 – most not drugs)
- Circumstances to justify are fairly specific…
  - Cancer drugs typically covered as a matter of policy
  - 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...?



Other opportunities

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

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- Include in definition of “value” evidence of benefit in pop representative of people to be treated
- Esp. if “value” linked to price

- Clinical practice guidelines
  - ASCO
  - NCCN

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- 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…
  - Value framework / evidence assessment
  - Formulary tier
  - Reimbursement and patient cost-sharing
  - Other aspects of benefit design
- Can have pull to affect drug development trial design choices