Patient Registries Under CED: Checklist of Endless Difficulties

PARTNERSHIP TO FIGHT CHRONIC DISEASE

How Medicare CED Requirements Delay Patient Access to FDA-Approved Treatments

When the Centers for Medicare and Medicaid Services (CMS) issues national coverage determinations (NCDs) for FDA-approved drugs or devices, the agency also determines conditions for Medicare coverage – including patient eligibility, eligible healthcare providers, and other specifics that must be met. Sometimes these conditions can include a coverage with evidence development (CED) requirement, which limits Medicare coverage only to beneficiaries participating in an approved clinical research study.

Though only 27 active NCDs of the hundreds from 2005-2022 require CED, the significant delays and barriers to access caused by CEDs can impact millions of patients and their families.

TIME TO FIRST PATIENT ENROLLMENT IN PAST CED SCENARIOS WITH REGISTRIES:

- National Oncologic PET Registry (NOPR): **18 months**
- IDEAS PET Registry: **23 months**
- NEW IDEAS PET Registry: **24 months**

Timelines do not include the 9-12 months required to establish CED.

Checklist to Establish Coverage with Evidence Development Clinical Study Registries

- ❑ CMS announces a NCD with CED
- ❑ Informal selection of a convening organization[3]
- ❑ Select primary investigators[3]
- ❑ Establish study governance*
- ❑ Conceptualize and agree on CED study protocol*
- ❑ Write a study protocol[3]
- ❑ Review and revise protocol with stakeholders*
- ❑ Study governance approval of initial protocol[3]
- ❑ Submit the protocol to CMS[3]
- ❑ CMS reviews and redlines per CMS response timelines[3]
  - » Multiple rounds of CMS review & revisions*
  - » Study stakeholders and/or governance reviews and responds to CMS revisions*
- ❑ Register with clinicaltrials.gov[3]
- ❑ CMS approval of study protocol[3]
- ❑ Build a study database[3]
- ❑ Develop data collection forms[3]
- ❑ Establish an Institutional Review Board (IRB) process (central or local)[3]
- ❑ Select an IRB vendor (if centralized)[3]
- ❑ Align on a funding operational structure*
  - » Obtain funding source
  - » Conceptualize funding model*
  - » Confirm funding operational structure
  - » Establish funding contracts with all necessary stakeholders*
- ❑ Develop educational materials for clinicians and/or patients*
- ❑ Launch CED study[3]
- ❑ Identify clinical sites and health care providers
  - » Site IRB approval[1]
  - » Clinician registration[1]
  - » Site and/or provider training[2]
- ❑ Identify patients who meet study criteria[1]
  - » Confirm eligible patients
  - » Patient consent[1]
  - » Confirm patient enrollment[3]
- ❑ Medicare covers treatment
  - » Patient receives treatment

Whose involvement is required at each step?

[1] Study participants
[2] Study sponsors (trainer) and study participants (trainee)
[3] Study sponsors
* Steps that require multi-stakeholder input

Source: Adapted from Façade of Evidence: How Medicare's Coverage with Evidence Development Paradigm Rations Care and Exacerbates Inequity. Alliance for Aging Research. Feb. 13, 2023.

MEDICARE BENEFICIARIES SHOULDN'T HAVE TO WAIT TO ACCESS FDA-APPROVED TREATMENTS. CED REQUIREMENTS ARE NOT THE ANSWER. LEARN MORE AT WWW.FIGHTCHRONICDISEASE.ORG.