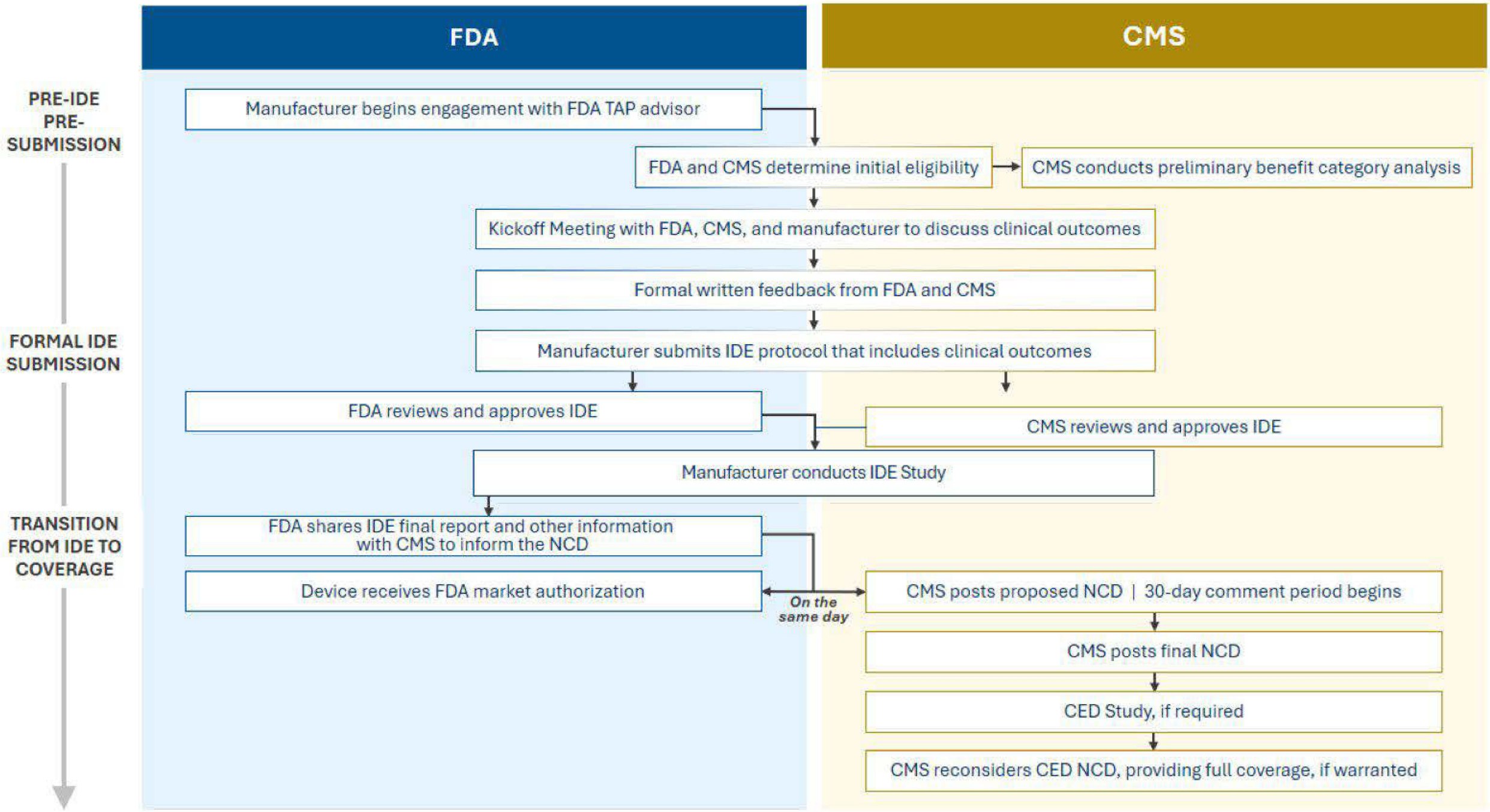
FDA
CMS
PRE-IDE PRE-SUBMISSION
FORMAL IDE SUBMISSION
TRANSITION FROM IDE TO COVERAGE
Manufacturer begins engagement with FDA TAP advisor
FDA and CMS determine initial eligibility
CMS conducts preliminary benefit category analysis
Kickoff Meeting with FDA, CMS, and manufacturer to discuss clinical outcomes
Formal written feedback from FDA and CMS
Manufacturer submits IDE protocol that includes clinical outcomes
FDA reviews and approves IDE
CMS reviews and approves IDE
Manufacturer conducts IDE Study
FDA shares IDE final report and other information with CMS to inform the NCD
Device receives FDA market authorization
On the same day
CMS posts proposed NCD | 30-day comment period begins
CMS posts final NCD
CED Study, if required
CMS reconsiders CED NCD, providing full coverage, if warranted