Defining CED

23 Coverage with Evidence Development (CED) determinations- As part of the national coverage determination (NCD) CMS may regulate coverage of an item or service only in the context of an approved clinical trial or centralized registry, unrelated to an approved clinical trial. Specific claims processing requirements for Medicare patients apply. Non-Medicare patients may enroll in the registry, and receive procedure, but claims processing logic does not apply.

- Part I- IRB approved protocol and Qualifying Clinical Trial (QCT)
  - Investigational Device Exemption (IDE)- TAVR (17 studies), TMVR (1 study), LAAC/LAAO (1 study), MRA/MRI (1 study)
  - Other studies (40 studies)
- Part II- IRB approved protocol and non-Qualifying Clinical Trial (non-QCT)
  - Leadless pacemaker (Micra System)- (2 studies recently approved: Feb and March 2017)
- Part III- no research association and registry requirement (Registry only)
  - TAVR, TMVR, LAAC/LAAO

Medicare claims processing logic

	Inpatient HB			Outpatient HB			PB		
	QCT	Non-QCT	Registry only	QCT	Non-QCT	Registry only	QCT	Non-QCT	Registry only
NCT#	x	x	x	x	x	x	x	x	x
CC30	x	x	x	x	x	x	x	x	x
Z00.6	x	x	x	x	x	x	x	x	x
Q0/Q1				x	x	x	x	x	x
Rev code 278		x	x		x	x			
Rev code 624	x			x					
IDE #				x			x		
HCPCS				x token charge code/ new EAP	x commercial use	x commercial use			

Note: other logic may apply to individual CEDs, confirm NCD specifics