

Medical Device Reimbursement

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Foundation Concepts

- Coding, coverage and reimbursement
 - Distinct but inter-related
- Few products concept → reimbursement
- FDA clearance/approval ≠ reimbursement
- Sending a bill ≠ payment

CCR

- Coding – a numbering system used to identify/define diagnoses, services, procedures and products
- Coverage – decisions on whether or not to pay for a service or product
- Reimbursement – the methods and amounts of payment for covered services and products

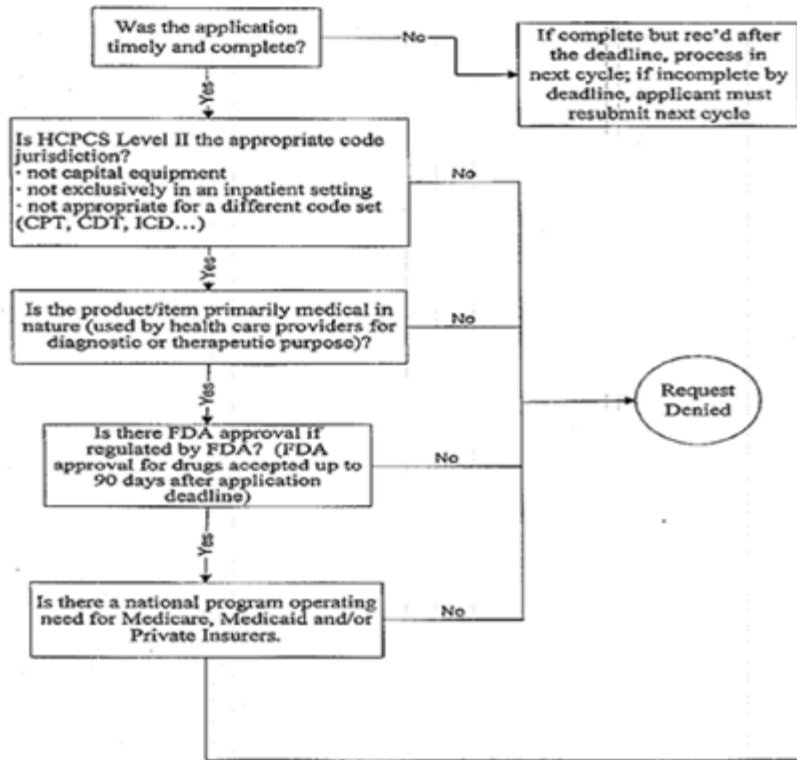
Coding

- Miscellaneous vs non-miscellaneous
 - Can get paid with misc.
 - Non-misc. code allows efficient processing
- Code may = coverage and payment
- Code \neq covered
- Code issuers
 - CPT- AMA – 2 years
 - HCPCS - CMS

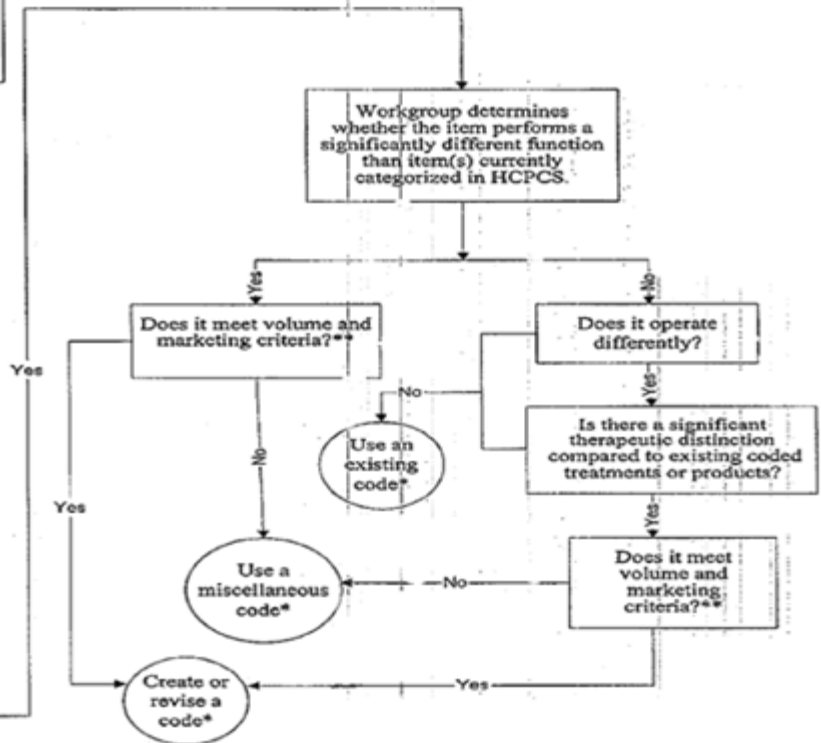
HCPCS Code

HCPCS Decision Tree For External Requests to Add or Revise Codes

TIER 1: Does the item that is the subject of the request belong in HCPCS Level II?



TIER 2: Which HCPCS Level II code should be used?



*Subject to national program operating need

**For drugs, volume and marketing criteria are waived, and "yes" is assumed for the purpose of following the decision tree

Coverage

- What clinical indications
- What documentation required
- Who can order/perform
- Local, national, payer-specific
- Medicare LCD/NCD
- T codes

Reimbursement

- Various methods
- Existing code with reimbursement
- Cross-walk
- Gap fill
- Through appeal

Case Example - Radiation Delivery Devices

- Device cleared by FDA
- No code for physician use so misc.
- Assigned a T-Code
- LCDs say all T-Codes to be denied
- Appealed denials
- Society included in practice guidelines
- Carriers developed coverage criteria
- Payments cross-walked

Case Example – DME Coverage

- Device cleared by FDA
- Couldn't use existing code for DME
- 2 years under misc. code → denied claims
- Appealed denied claims
- ALJ's found coverage
- No fee schedule – pay initial determination
- Payer begins drafting coverage policy