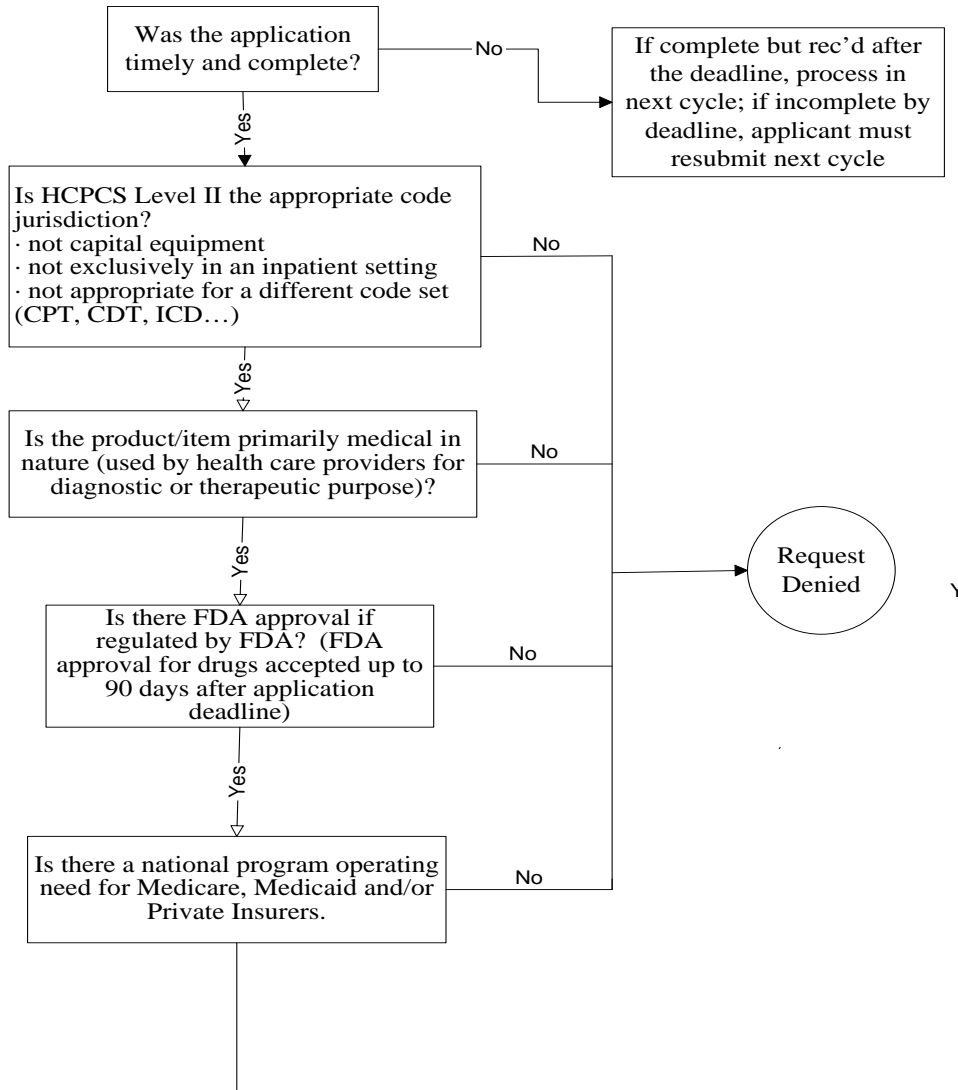
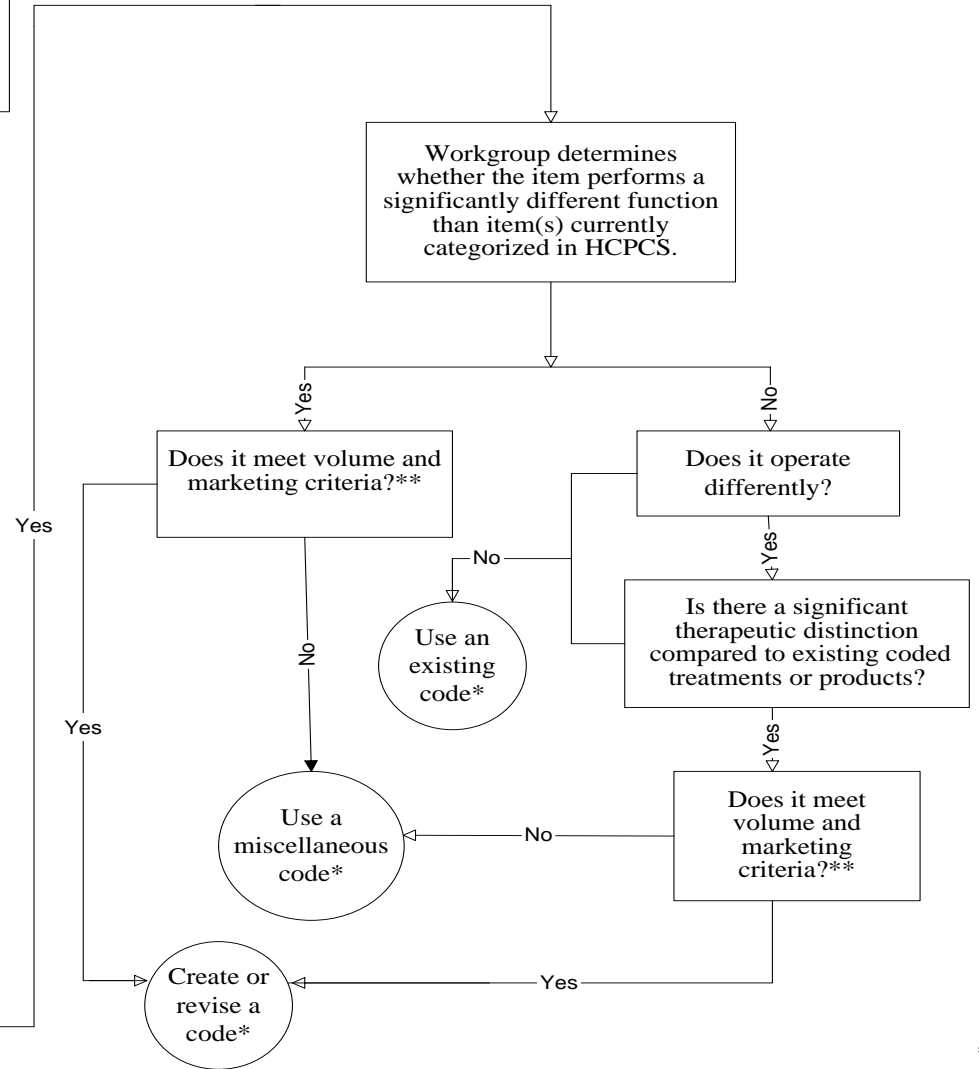


HCPCS Decision Tree For External Requests to Add or Revise Codes

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

Definitions and Clarifications

Tier 1:

HCPCS 2 is the appropriate code jurisdiction: Item is not within the jurisdiction of CPT, CDT, ICD or DRG coding.

Primarily Medical in nature: Item is primarily and customarily used to serve a medical purpose and is not useful in the absence of a medical condition or injury.

FDA approved if regulated: See the online Medicare Benefit Policy Manual #100.2, Chapter 15 – Covered Medical and Other Health Service, Section 50.4.1 – Approved Use of Drug. Does not apply if regulated items are not yet approved. Note: FDA approval for drugs accepted up to 90 days after the application deadline.

National Programmatic Need: At least one insurance sector, public (Medicare or Medicaid) or private (commercial insurers) identified a program operating need to separately identify the item and that need is common across the sector, (i.e., nationally, as opposed to one or a handful of individual insurers or states). Does not apply if item identification is statutorily required.

Tier 2:

Existing or similar code: Describes a similar function to previously coded products

Volume and marketing criteria: There must be sufficient claims activity or volume (3% of affected population), as evidenced by 3 months of marketing activity for non-drug products, so that the adding of a new or modified code enhances the efficiency of the system and justifies the administrative burden of adding or modifying a code and establishing policy and system edits.

Note: Marketing data requirements waived for drugs only.

Performs a different function: Does something completely different to the patient. Examples: suction for a different purpose; static vs. dynamic; swing vs. stance.

Operates differently: Performs the same or similar function to other items, using a different mechanism. Examples: mechanical vs. electronic; automatic vs. manual regulating; extrinsic vs. intrinsic lubrication.

Significant Therapeutic Distinction: Improved medical benefit when compared with the use of other, similar items, e.g., significantly improved medical outcome or significantly superior clinical outcome. Requests for modifications to the HCPCS Level II code set based on such claims are reviewed on a case-by-case basis, taking into consideration clinical information provided by the applicant and other commentators that supports or refutes the claim(s) made by the applicant. In submitting a request, an applicant should provide the best available information supporting his or her claim. Greater weight will be given to more methodologically rigorous and scientifically reliable evidence. Note that process indicators (such as improved compliance, convenience and personal preference) are considered significant distinctions only to the extent that they result in demonstrably improved clinical outcomes.