

EFFECTIVE DATE: $04 \mid 05 \mid 2011$ **POLICY LAST UPDATED**: $02 \mid 10 \mid 2021$

OVERVIEW

This intent of this policy is to identify coverage determinations for CPT codes that represent new and emerging technologies.

MEDICAL CRITERIA

Medicare Advantage Plans and Commercial Products

For services that require prior authorization, please refer to the Related Policies identified in the Code and Coverage Grid found in the Coding Section of this policy for appropriate medical criteria.

PRIOR AUTHORIZATION

Medicare Advantage Plans and Commercial Products

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POLICY STATEMENT

Medicare Advantage Plans

BCBSRI coverage categories for procedure codes for new and existing unproven technology include the following:

- Covered:
- Not Covered as the evidence is insufficient to determine the effects of the technologies on health outcomes
- Preauthorization is required;
- Not separately reimbursed;
- Use alternate procedure code

Commercial Products

BCBSRI coverage categories for procedure codes for new and existing unproven technology include the following:

- Covered;
- Not Covered and a contract exclusion;
- Not medically necessary as the evidence is insufficient to determine the effects of the technologies on health outcomes;
- Preauthorization is recommended;
- Not separately reimbursed;
- Use alternate procedure code

BACKGROUND

The majority of CPT codes included in this policy are Category III CPT codes. They are a set of temporary codes for emerging technology, services and procedures. Category III CPT codes allow data for these services/procedures. The use of unlisted codes does not offer the opportunity for the collection of specific data. If a Category III code is available, this code must be reported instead of a Category I unlisted code.

The use of Category III CPT codes allows physicians and other qualified health care professionals, insurers, health services researchers and health policy experts to identify emerging technologies, services and procedures for clinical efficacy, utilization and outcomes.

The inclusion of a service or procedure within the section of Category III does not constitute a finding of support, or lack thereof, with regard to clinical efficacy, safety, applicability to clinical practice or payer coverage.

The nature of emerging technologies, services and procedures is such that the requirements for CPT Category I codes established by the Editorial Panel may not be met, such as:

- Service/procedure be performed by many health care professionals in clinical practice in multiple
- FDA approval has already been received.

Category III CPT codes may or may not eventually receive a Category I CPT code. In general, a given Category III code will be archived five years from the date of initial publication or extension unless a modification of the archival date is specifically noted at the time of a revision or change to a code. Services and procedures described by Category III codes which have been archived, without conversion to a Category I codes, must be reported using a Category I unlisted code unless another specific cross-reference is established at the time of archiving. New or revised codes in this section are released semi-annually via the AMA CPT website.

Items and services must be established as safe and effective to be considered medically necessary. That is, the items and services must be:

- Consistent with the symptoms of diagnosis of the illness or injury under treatment;
- Necessary for, and consistent with, generally accepted professional medical standards of care (e.g., not
- Not furnished primarily for the convenience of the patient or of the provider or supplier; and
- Furnished at the most appropriate level of care that can be provided safely and effectively to the patient.

A treatment or procedure is considered not medically necessary if reliable evidence shows that prevailing opinion among experts regarding the treatment is that more studies or clinical trials are necessary to determine its safety, efficacy, toxicity, maximum tolerated dose, or its efficacy as compared with a standard means of treatment or diagnosis.

Medicare Advantage Plans Investigational Devices

Category A devices, as categorized by the U.S. Food and Drug Administration, are considered not medically reasonable and necessary and are therefore not covered.

Category A (Experimental) device, which refers to a device for which "absolute risk" of the device type has not been established (that is, initial questions of safety and effectiveness have not been resolved) and the FDA is unsure whether the device type can be safe and effective.

Category B devices may be covered if they are considered medically reasonable and necessary and all other applicable Medicare coverage requirements are met.

Category B (Non-experimental/investigational) device, which refers to a device for which the incremental risk is the primary risk in question (that is, initial questions of safety and effectiveness of that device type have been resolved), or it is known that the device type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable "Health Care Services Not Covered" coverage/benefits.

CODING

See the attached grid for Medicare Advantage Plans and Commercial Products coverage of new and existing unproven technology.

New Technology and Miscellaneous Codes and Coverage

RELATED POLICIES

Medicare Advantage Plans National and Local Coverage Determinations Medical Necessity

PUBLISHED

Provider Update, March 2021 Provider Update, April 2020 Provider Update, September 2018 Provider Update, January 2018 Provider Update, January 2017

REFERENCES

American Medical Association (AMA) Current Procedural Terminology, cpt® 2018, Professional Edition

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