Medical Coverage Policy | New Technology, (formerly CPT Category III Codes)

EFFECTIVE DATE: 04|05|2011
POLICY LAST UPDATED: 12|05|2017

OVERVIEW

The CPT codes included in this policy are health service codes for new and emerging technologies. The codes have been created to allow for various indications such as data to determine coverage for those devices, treatments, or procedures for which the safety and efficacy have been proven, and which are comparable or superior to conventional therapies.
Any device, medical treatment, supply or procedure for which safety and efficacy has not been established and proven is considered not medically necessary and is excluded from coverage.

PRIOR AUTHORIZATION

See chart in attachment below

POLICY STATEMENT

BlueCHiP for Medicare
BCBSRI coverage categories for procedure codes for new and existing unproven technology include the following:
• Covered;
• Not Covered and a contract exclusion;
• Not Covered as they are not FDA approved;
• Not medically necessary as there is insufficient clinical data available to support its efficacy;
• Preauthorization is required; or
• Not separately reimbursed.
• Use alternate procedure code

OR

Not medically necessary based on the following indications;
• Not generally accepted by the medical community as safe and effective in the setting and for the condition for which it is used;
• Not proven safe and effective based on peer review or scientific literature;
• Not medically necessary for a particular patient;
• Furnished at a level, duration, or frequency that is not medically appropriate;
• Not furnished in accordance with accepted standards of medical practice; or
• Not furnished in a setting appropriate to the patient's medical needs and condition.

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 experimental);
• Not furnished primarily for the convenience of the patient or of the provider or supplier.

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 Covered as they are not FDA approved;
- Not medically necessary as there is insufficient clinical data available to support its efficacy;
- Preauthorization is required; or
- Not separately reimbursed.
- Use alternate procedure code

MEDICAL CRITERIA

BlueCHiP for Medicare and Commercial Products

None

BACKGROUND

Category III codes are different from Category I CPT codes in that they identify services that may not be performed by many health care professionals across the country, some may not have FDA approval, and some services/procedure have no proven clinical efficacy. The codes are intended to be temporary and will be retired if the procedure or service is not accepted as a Category I code within five years. In some instances Category III codes may replace temporary local codes (HCPCS Level III) assigned by carriers and intermediaries to describe new procedures or services. If a Category III code is available it must be used instead of the unlisted Category I code. The use of the unlisted code does not offer the opportunity for collection of specific data. The AMA releases new codes twice a year (January and July) on its Web site.

Medicare 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 he 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 thedevice type can be safe and effective because, for example, other manufacturers have obtained FDA premarket approval or clearance for that device type.

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.

COVERAGE

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

CODING

See attachment below for coverage of all CPT codes for new and existing unproven technology.

2018 CPT III coverage_Final_0116

RELATED POLICIES

Medical Necessity
See grid for other related policies
All Codes for New Technology included in the attachment below

PUBLISHED

Provider Update, January 2018
Provider Update, January 2017
Provider Update, January 2016
Provider Update, January 2013
Provider Update, June 2011

REFERENCES:

None.

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