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Medicare Advantage Policy Manual

TOPIC: Investigational (Experimental) Services and New and Emerging Medical Technologies and Procedures

Section: Medicare Manual – Medicine Approval Date: June 2017
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IMPORTANT REMINDER: The health plan’s Medicare Advantage Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with the member Evidence of Coverage (EOC) booklet. Benefit determinations are based in all cases on any applicable EOC language and any applicable CMS policy. To the extent there may be any conflict, applicable EOC language or applicable CMS policy take precedence over the health plan’s Medicare Advantage Medical Policy.

MEDICARE MEDICAL POLICY CRITERIA

Note: This Medicare Advantage medical policy does not address services provided in the context of a clinical trial, or medical devices related to Category A or B Investigational Device Exemption (IDE) studies. For Clinical Trial and IDE study claim assistance, see the Centers for Medicare and Medicaid Services (CMS) website.

Procedures and items that are subject to Coverage with Evidence Development (CED) criteria may be addressed in separate Medicare Advantage medical policies when those services are reviewed by the health plan. National coverage determinations (NCDs) that require CED can be found on the CMS web page for Coverage with Evidence Development.

Investigational Services:

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) prohibits Medicare coverage for items and services which are not “reasonable and necessary” for the diagnosis and treatment of an injury or illness or to improve the functioning of a malformed body member. According to the Medicare Claims Processing Manual, Chapter 23, §30.A, if a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental,
the service is noncovered because it is not reasonable and necessary to treat illness or injury.\(^2\)

In the absence of a national coverage determination (NCD), local coverage determination (LCD), or other Medicare coverage guidance, Medicare regulations allow a Medicare Advantage Organization (MAO) to make its own coverage determination, applying an objective, evidence-based process, based on authoritative evidence.\(^3\)

Note, the issuance of a CPT code or the presence of a payment amount in the Medicare Physicians’ Fee Schedule (MPFS) does not imply that Medicare has determined the service to be a “reasonable and necessary” covered service.\(^2\) Requests for health care services, treatments, procedures, or devices that are not addressed in an NCD, LCD, or other Medicare reference, or not specified as “covered” in Medicare benefit manuals or other transmittals may be reviewed to ensure sufficient evidence regarding safety and efficacy is available, ensuring the services are medically reasonable and necessary for members.

In order to determine whether a medical technology is a proven, medically necessary service, device, or procedure, the MAO conducts literature searches and evaluates the published scientific evidence related to each technology. The published evidence is reviewed against five (5) technology assessment criteria. In order for a technology to be considered medically necessary, all five (5) criteria must be met. If any one or more of the following criteria are not met, then the technology is considered investigational:

1. The technology must have final approval from the appropriate government regulatory bodies (i.e., Food and Drug Administration [FDA]). An approval granted as an interim step (i.e., Treatment IND) in the governmental body’s regulatory process is not sufficient.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes, and consist of well-designed and well-conducted investigations published in peer-reviewed journals. The quality of the studies and the consistency of the results are considered when evaluating the evidence.
3. The technology must improve the net health outcome (the technology’s beneficial effects on health outcomes should outweigh any harmful effects on health outcomes).
4. The technology must be as beneficial as any established alternatives. This means the technology should improve the net health outcome as much as or more than established alternatives.
5. The improvement must be attainable outside the investigational settings. When used under the usual conditions of medical practice, the technology should be reasonably expected to satisfy technology evaluation criteria #3 and #4.
In addition to the above criteria, the following additional criteria apply to new diagnostic technologies (e.g., imaging studies, laboratory procedures, home monitoring devices):

1. Technical feasibility is demonstrated, including reproducibility and precision. For comparison among studies, a common standardized protocol for the new diagnostic technology is established.
2. For accurate interpretation of study results, sensitivities, specificities, and positive and negative predictive values compared to standards are established.
3. The clinical utility of a diagnostic technique, i.e., how the results of the study can be used to benefit patient management, is established. The clinical utility of both positive and negative tests must be established.

The following are new and emerging medical technologies reported with Category III CPT Codes. According to the Noridian Local Coverage Determination (LCD) for Non-Covered Services (L35008), all new Category III Codes are considered non-covered unless specifically approved for payment by CMS or the Noridian Healthcare Solutions (Noridian) medical directors and documented as approved in a published LCD or article (LCA). In most cases, these codes have been created to track new, unproven therapies and tests.

**Note:** The absence of a Category III code from this medical policy does not imply coverage. See the Noridian LCD for Non-Covered Services (L35008) for the coverage status of additional Category III codes.

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>CPT</td>
<td>0346T</td>
<td>Ultrasound, elastography (List separately in addition to code for primary procedure)</td>
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<tr>
<td></td>
<td>0469T</td>
<td>Retinal polarization scan, ocular screening with on-site automated results, bilateral</td>
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<tr>
<td></td>
<td>0470T</td>
<td>Optical coherence tomography (OCT) for microstructural and morphological imaging of skin, image acquisition, interpretation, and report; first lesion</td>
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<tr>
<td></td>
<td>0471T</td>
<td>; each additional lesion (List separately in addition to code for primary procedure)</td>
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<tr>
<td></td>
<td>0472T</td>
<td>Device evaluation, interrogation, and initial programming of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, with iterative adjustment of the implantable device to test functionality, select optimal permanent programmed values with analysis, including visual training, with review and report by a qualified health care professional</td>
</tr>
<tr>
<td></td>
<td>0473T</td>
<td>Device evaluation and interrogation of intra-ocular retinal electrode array (eg, retinal prosthesis), in person, including reprogramming and...</td>
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</table>
visual training, when performed, with review and report by a qualified health care professional

0474T Insertion of anterior segment aqueous drainage device, with creation of intraocular reservoir, internal approach, into the supraciliary space

0475T Recording of fetal magnetic cardiac signal using at least 3 channels; patient recording and storage, data scanning with signal extraction, technical analysis and result, as well as supervision, review, and interpretation of report by a physician or other qualified health care professional

0476T ; patient recording, data scanning, with raw electronic signal transfer of data and storage

0477T ; signal extraction, technical analysis, and result

0478T ; review, interpretation, report by physician or other qualified health care professional

REFERENCES

1. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §10.7.3 – Payment for Clinical Studies Approved Under Coverage with Evidence Development (CED)

2. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician’s Fee Schedule, A. Physician’s Services

3. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.5 – Creating New Guidance

4. Noridian LCD for Non-Covered Services (L35008) (This LCD can be found on the Medicare Coverage Database website)

CROSS REFERENCES


Clinical Trials and Investigational Device Exemption (IDE) Studies, Medicine, Policy No. M-150

Coverage with Evidence Development (CED) Studies and Registries, Medicine, Policy No. M-156

Various Medicare Advantage medical policies