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Medicare Advantage Policy Manual

Policy ID: M-RAD59

Cone Beam Computed Tomography of the Breast

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Cone beam computed tomography (CT) provides three dimensional images for the diagnosis of breast cancer in patients with signs or symptoms of disease and individuals who have abnormal imaging findings.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None ^[1]
	According to NCD 220.1, examinations performed by computerized tomography (CT) scanners may be covered when medical and scientific literature and opinion support the effective use of a scan for the condition, the scan is deemed reasonable and necessary for the individual patient, and when performed on

a model of CT equipment that meets specified FDA-approval and marketing requirements. This NCD does not provide evidence-based data or other scientific literature regarding cone beam breast CT. Therefore, the health plan's medical policy provides this information below.

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles*

None^[2]

The LCD L35175 focuses on CT scans on the *head and neck* and therefore, wouldn't apply to *breast* CT technologies.

Medical Policy Manual

Medicare coverage guidance is not available for cone beam breast CT. Therefore, the health plan's medical policy is applicable.

Cone Beam Breast Computed Tomography for Breast Cancer Diagnosis, Radiology, [Policy No. 59](#) (see "NOTE" below)

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. ([Medicare IOM Pub. No. 100-04, Ch. 23, §30 A](#)). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an **objective, evidence-based process, based on authoritative evidence**. ([Medicare IOM Pub. No. 100-16, Ch. 4, §90.5](#)). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

In 2015, the U.S. Food and Drug Administration (FDA) approved the Koning Breast CT (CBCT1000) under the PMA process for three-dimensional diagnostic imaging of the breast.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

[Investigational \(Experimental\) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services](#), Medicine, Policy No. M-149

REFERENCES

1. NCD for *Computed Tomography (220.1)* [Last Cited 12/20/2023] (*This NCD can be accessed directly from the [Medicare Coverage Database](#) website*)
2. Noridian LCD for *MRI and CT Scans of the Head and Neck (L35175)* [Last Cited 12/20/2023] (*This LCD can be accessed directly from the [Medicare Coverage Database](#) website*)
3. MLN Fact Sheet for APPROPRIATE USE CRITERIA FOR ADVANCED DIAGNOSTIC IMAGING; Available at: <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/AUCDiagnosticImaging-909377.pdf> [Last Cited 12/20/2023]

CODING

Codes	Number	Description
CPT	0633T	Computed tomography, breast, including 3D rendering, when performed, unilateral; without contrast material
	0634T	; with contrast material(s)
	0635T	; without contrast, followed by contrast material(s)
	0636T	Computed tomography, breast, including 3D rendering, when performed, bilateral; without contrast material(s)
	0637T	; with contrast material(s)
	0638T	; without contrast, followed by contrast material(s)
HCPCS	None	

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.