Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MP189

Section: Medical Benefit Policy

Subject: Computer Aided Detection Technology

I. Policy: Computer Aided Detection Technology

II. Purpose/Objective:

To provide a policy of coverage regarding Computer Aided Detection Technology

III. Responsibility:

- A. Medical Directors
- **B.** Medical Management

IV. Required Definitions

- 1. Attachment a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
- 2. Exhibit a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
- 3. Devised the date the policy was implemented.
- 4. Revised the date of every revision to the policy, including typographical and grammatical changes.
- 5. Reviewed the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions

Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

- a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
- b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
- c. in accordance with current standards of good medical treatment practiced by the general medical community.
- d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
- e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment

Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

- (i) The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
- (ii) The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
- (iii) The service or benefit will assist the Member to achieve or maintain maximum functional

capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

DESCRIPTION:

The computer-aided detection (CAD) system uses computerized algorithms to identify suspicious regions of interest on imaging studies. The CAD system is intended to be used only after a radiologist has completed an evaluation of the image. Although CAD is most often used in mammography, various new devices are now being developed for the detection of lesions in medical imaging including conventional radiology, CT, MRI and ultrasound studies.

INDICATIONS:

The use of computer aided detection in conjunction with a mammography and/or Breast MRI studies may be considered medically necessary when used to assist the radiologist in detecting potential abnormalities.

EXCLUSIONS:

The Plan does **NOT** provide coverage for the use of a computer-aided detection system in imaging studies other than mammography, including but not limited to X-rays, CT, MRI, and ultrasound studies. There is insufficient evidence in the peer-reviewed published medical literature regarding the effectiveness of the application of CAD technology to imaging studies other than mammography. It is considered **unproven** and **NOT COVERED**.

Note: A complete description of the process by which a given technology or service is evaluated and determined to be experimental, investigational or unproven is outlined in MP 15 - Experimental Investigational or Unproven Services or Treatment.

CODING ASSOCIATED WITH: Computer Aided Detection Technology

The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

HCPCS/CPT Codes:

- 0159T Computer aided detection, including computer algorithm analysis of MRI image data for lesion detection/characterization, pharmacokinetic analysis, with further physical review for interpretation, breast MRI.
- 0174T Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s). Performed concurrent with primary interpretation. (List separately in addition to code for primary procedure)
- 0175T Computer-aided detection (CAD) (computer algorithm analysis of digital image data for lesion detection) with further physician review for interpretation and report, with or without digitization of film radiographic images, chest radiograph(s). Performed remote from primary interpretation.
- 77065 Diagnostic mammography, including computer-aided detection (CAD) when performed; unilateral
- 77066 Diagnostic mammography, including computer-aided detection (CAD) when performed; bilateral
- 77067 Screening mammography, bilateral (2-view study of each breast), including computer-aided detection (CAD) when performed

Current Procedural Terminology (CPT®) © American Medical Association: Chicago, IL

LINE OF BUSINESS:

Eligibility and contract specific benefits, limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD's and NCD's will supercede this policy. For PA Medicaid Business segment, this policy applies as written.

Gold Choice: Coverage will be in accordance with current CMS guidelines.

REFERENCES:

"CAD for Mammography", Geisinger Technology Assessment Committee, October, 10, 2001.

Demartini WB, Lehman CD, Peacock S, Russell MT. Computer-aided detection applied to breast MRI: assessment of CAD_generated enhancement and tumor size in breast cancers before and after neoadjuvant chemotherapy. Acad Radiol. 2005 Jul;12(7):806-14.

Dean JC, Ilvento CC. Improved cancer detection using computer-aided detection with diagnostic and screening mammography: Prospective Study of 104 Cancers.

Birdwell RL, Bandodkar P, Ikeda DM. Computer-aided detection with screening mammography in a university hospital setting. Radiology 2005;236:451-457.

Morton MJ, Whaley DH, Brandt KR, Amrami KK. Screening Mammograms: Inerpretation with computer-aided detectionprospective evaluation. Radiology 2006 May;239(2):375-383.

Technology Evaluation Center (TEC). Computer-aided detection of malignancy with magnetic resonance imaging of the breast. 2006 June;21(4): Blue Cross Blue Shield Association.

Shiraishi J, Abe H, Engelmann R, Doi K. Effect of high sensitivity in a computerized scheme for detecting extremely subtle solitary pulmonary nodules in chest radiographs: observers performance study. Acad Radiol. 2003 Nov;10(11):1302-11.

Brown MS, Goldin JG, Rogers S, Kim HJ, Suh RD, McNitt-gray MF, Shah SK, Truong D, Brown K, Sayre JW, Gjertson DW, Batra P, Aberle DR. Computer-aided lung nodule detection in CT: results of large-scale observer test. Acad Radiol. 2005 June;12(6):669-70.

Kakeda S, Moriya J, Sato H, Aoki T, Wantanabe H, nakata H, Oda N, Katsuragawa S, Yammamoto K, Doi K. Improved detection of lung nodules on chest radiographs using a commercial computer-aided diagnosis system. AJR Am J Roentgenol. 2004 Feb;182(2):505-10.

Technology Evaluation Center (TEC). Computer-aided detection (CAD) in Mammography; December 2002; 17(17): Blue Cross Blue Shield Association.

Fenton JJ. Taplin SH, Carney PA, Abraham L, Sickles EA, D'Orsi C, Berns EA, Cutter G, Hendrick E, Barlow WE, Elmore JG. Influence of computer-aided detection on performance of screening mammography. N Engl J Med 356;14:1399-1409.

ECRI Institute. Emerging Technology (TARGET) Evidence Report (online) Computer-assisted detection (CAD) with magnetic resonance imaging (MRI) to detect breast cancer. ECRI Institute. Current as of October 2007.

Gilbert FJ, Astley SM, Gillan MGC, et al. Single Reading with Computer-Aided Detection for Screening Mammography. NEJM 2008;359:1675-84.

ECRI Institute. Computer-aided Detection Mammography for Breast Cancer Screening. ECRI Institute. Current as of October 19, 2010.

Yun SJ, Sohn YM, Seo M. Differentiation of benign and metastatic axillary lymph nodes in breast cancer: additive value of MRI computer-aided evaluation. Clin Radiol. Apr 2016;71(4):403 e401-407.

This policy will be revised as necessary and reviewed no less than annually.

Devised: 09/2006

Revised:

Reviewed: 03/10, 3/11, 3/12, 3/13, 3/14, 3/15, 3/16, 3/17, 2/18, 2/19, 2/20