MEDICAL POLICY

POLICY TITLE	MAMMOGRAPHY (INCLUDING COMPUTER AIDED DETECTION MAMMOGRAPHY AND POSITRON EMISSION MAMMOGRAPHY)
POLICY NUMBER	MP-5.008

Original Issue Date (Created):	**7/1/2002**
Most Recent Review Date (Revised):	**12/11/2018**
Effective Date:	**2/1/2019**

I. POLICY

Note: Refer to Capital Blue Cross's Health Maintenance Guidelines for recommendations concerning the use of mammography for screening indications for adult Members covered under commercial products.

A mammogram may be considered **medically necessary**, regardless of age if the patient has the following:

- A personal history of breast cancer; or
- Exhibits distinct symptoms for which a mammogram is indicated such as (but not limited to) the following:
  - Breast mass or nodes;
  - Tender or painful breasts;
  - Nipple discharge; or
  - Change in the color, surface size and/or shape of the breast, skin, or nipple.

A mammogram may be considered **medically necessary** and appropriate regardless of age for patients with:

- A history or presence of endometrial cancer; or
- Metastases or nodes in areas of the body other than the breast; or
- A history of previous suspicious lesions or masses of the breast; or
- In cases where palpation is impaired due to large, fatty breasts, implanted or augmented breasts.

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A mammogram may be considered **medically necessary** for a patient with fibrocystic disease that is experiencing any of the aforementioned symptoms or conditions.

Direct full-field digital mammography may be considered **medically necessary**, both as a screening or diagnostic technique.

Computer-Aided Detection Mammography
Computer-assisted detection devices used as an adjunct to single-reader interpretation of digitized film screening mammograms, or used as an adjunct to single-reader interpretation of direct, full field digital mammography may be considered **medically necessary**.

Positron Emission Mammography (PEM)

The use of positron emission mammography (PEM) is considered **investigational.** There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

***Cross References*:**

MP-5.021 Scintimammography /Breast Specific Gamma Imaging/Molecular Breast Imaging
MP-5.058 Computer-Aided Evaluation of Malignancy as an Adjunct to Magnetic Resonance Imaging of the Breast

II. PRODUCT VARIATIONS Top

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO - Refer to FEP Medical Policy Manual MP-6.01.53, Digital Breast Tomosynthesis and MP- 6.01.52, Positive Emission Mammography (PEM). The FEP Medical Policy Manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

NOTE: On October 5, 2015, the Pennsylvania Insurance Department provided guidance to health Insurers regarding coverage of 3D Mammography (Digital Breast Tomosynthesis) Under this state law, 3D mammograms, also known as digital breast tomosynthesis, must be covered at no cost in the same manner as traditional two-dimensional mammograms.

NOTE: All members may self-refer to a participating provider for their screening mammograms, including a baseline mammogram between ages 35-39.

III. DESCRIPTION/BACKGROUND Top

A mammogram is an x-ray image of the breast. A screening mammogram is used to detect early breast cancer in asymptomatic women. Diagnostic mammography is used to tailor the mammographic examination to evaluate patients with breast symptoms. Symptoms can include

breast pain, nipple discharge, or palpable masses. Diagnostic mammograms are also used to clarify potential abnormalities detected on screening studies and for evaluating patients with past history of breast cancer.

The Mammography Act (Act 148 of 1992) is a Pennsylvania state mandate, which requires insurers to provide for one annual mammogram for women age forty (40) and over and for any other mammogram recommended by a physician for women under age forty (40).
Early detection of breast cancer reduces morbidity and mortality.

Film Screen Mammography
Film screen mammography refers to the use of radiosensitive phosphors and film emulsion systems to capture an x-ray image on film. Full screen digital mammography refers to the use of radiosensitive digital detectors to capture and store the x-ray image for display on high-resolution CRT monitors without the use of film. As of 2005, both have been shown to be equivalent for the detection of breast cancer.

Computer-Aided Detection Mammography

Screening mammograms have a wide variability in interpretation and accuracy among radiologists. Some of the reasons for this include the complex radiographic structure of the breast. Computer-assisted diagnosis (CAD) has been suggested as an adjunct to screening mammograms to decrease errors in perception (i.e. failure to see an abnormality). Studies have shown that CAD increases the number of cancers detected during screening mammography. Early detection of cancer allows for early treatment interventions, which may lead to a higher cure rate.

The use of CAD systems requires a digitized image, either generated by digitization of a screening film mammogram, or generated directly. Commercially available CAD systems then use computerized algorithms for identifying suspicious regions of interest on the digital image. The locations of the abnormalities are marked such that the reader can then reference the same areas in the original mammogram for further review. The intent of CAD is to aid in detection of potential abnormalities for the radiologist to re-review. CAD systems are not designed to replace original mammograms or to replace the radiologist's reading. The radiologist, not CAD, makes the diagnosis if a clinically significant abnormality exists and determines whether future diagnostic evaluation is warranted.

The distinction between digitized screen-film mammograms (SFM) and direct full-field digital mammograms (FFDM) is important. Since these two images are generated in different ways, the associated diagnostic performance of adjunctive CAD must be considered separately. Conceptually, the CAD systems used with digital mammography are very similar to those used with film mammography. The computer analyzes the digital images collected directly by the FFDM system, applies a set of algorithms that capture characteristics known to be associated potentially with malignancies, and produces an image with markings that show the site of suspicious findings. Sometimes, different marks are used for suspected masses and suspected

microcalcifications. The major difference between CAD for FFDM and CAD for SFM is the extensive data set provided by the former and its interaction with the CAD algorithms.

Positron Emission Mammography (PEM)

Positron emission mammography (PEM) is a form of positron emission tomography (PET) that uses a high-resolution, mini-camera detection technology for imaging the breast. As with PET, a radiotracer (usually fluorine 18 fluorodeoxyglucose) is administered, and the camera is used to provide a higher resolution image of a limited section of the body than would be achievable with fluorine 18 fluorodeoxyglucose PET. Gentle compression is used, and the detector(s) are mounted directly on the compression paddle(s).[1-3]

PEM was developed to overcome the limitations of PET for detecting breast cancer tumors. Patients are usually supine for PET procedures; further, breast tissue may spread over the chest wall, making it potentially difficult to differentiate breast lesions from other organs that take up the radiotracer. PET's resolution is generally limited to approximately 5 mm, which may not detect early breast cancer tumors.[4] PEM allows for the detection of lesions as small as 2 to 3 mm and creates images that are more easily compared with mammography because they are acquired in the same position.[2,5] Three-dimensional reconstruction of PEM images also is possible. As with PET, PEM provides functional rather than anatomic information about the breast.[1-3] In PEM studies, exclusion criteria have included some patients with diabetes (e.g., Berg et al [2011, 2012][6,7]).

Radiation Dose Associated With PEM

The label-recommended dose of FDG for PEM is 370 MBq (10 mCi). Hendrick (2010) calculated mean glandular doses, and from the doses was able to determine lifetime attributable risk (LAR) of cancer for film mammography, digital mammography, breast-specific gamma imaging (BSGI), and PEM.8 The author used BEIR VII Group risk estimates9 to gauge the risks of radiation-induced cancer incidence and mortality from breast imaging studies. Estimated LAR of cancer for a patient with average-sized compressed breast during mammography of 5.3 cm (risks would be higher for larger breasts) for a single breast procedure at age 40 years is:

- 5 per 100,000 for digital mammography (breast cancer only);
- 7 per 100,000 for screen film mammography (breast cancer only);
- 55 to 82 per 100,000 for BSGI (depending on the dose of technetium 99m sestamibi); and
- 75 per 100,000 for PEM.

The corresponding LAR of cancer mortality at age 40 years is:

- 1.3 per 100,000 for digital mammography (breast cancer only);
- 7 per 100,000 for screen film mammography (breast cancer only);
- 26 to 39 per 100,000 for BSGI; and
- 31 per 100,000 for PEM.

A major difference in the impact of radiation between mammography and BSGI or PEM is that in mammography radiation dose is limited to the breast; whereas with BSGI and PEM, all organs are irradiated. Furthermore, as one ages, the risk of cancer induction from radiation exposure decreases more rapidly for the breast than for other radiosensitive organs. Organs at highest risk for cancer are the bladder with PEM and the colon with BSGI; these cancers, along with lung cancer, are also less curable than breast cancer. Thus, the distribution of radiation throughout the body adds to the risks associated with BSGI and PEM. Hendrick concluded that[8]:

> "… BSGI and PEM are not good candidate procedures for breast cancer screening because of the associated higher risks for cancer induction per study compared with the risks associated with existing modalities such as mammography, breast US [ultrasound], and breast MR [magnetic resonance] imaging. The benefit-to-risk ratio for BSGI and PEM may be different in women known to have breast cancer, in whom additional information about the extent of disease may better guide treatment."

O'Connor et al (2010) estimated the LAR of cancer and cancer mortality from the use of digital mammography, screen-film mammography, PEM, and molecular breast imaging.[10] Only results for digital mammography and PEM are reported here. The authors concluded that, in a group of 100,000 women at age 80 years, a single digital mammogram at age 40 years would induce 4.7 cancers with 1.0 cancer deaths; 2.2 cancers with 0.5 cancer deaths for a mammogram at age 50; 0.9 cancers with 0.2 cancer deaths for a mammogram at age 60; and 0.2 cancers with 0.0 cancer deaths for a mammogram at age 70. Comparable numbers for PEM would be 36 cancers and 17 cancer deaths for PEM at age 40; 30 cancers and 15 cancer deaths for PEM at age 50; 22 cancers and 12 cancer deaths for PEM at age 60; and 9.5 cancers and 5.2 cancer deaths for PEM at age 70. The authors also analyzed the cumulative effect of annual screening between the ages of 40 and 80, as well as between the ages of 50 and 80. For women at age 80 who were screened annually from the ages of 40 to 80, digital mammography would induce 56 cancers with 15 cancer deaths; for PEM, the analogous numbers were 800 cancers and 408 cancer deaths. For women at age 80 who were screened annually from the ages of 50 to 80, digital mammography would induce 21 cancers with 6 cancer deaths; for PEM, the analogous numbers were 442 cancers and 248 cancer deaths. However, background radiation from age 0 to 80 is estimated to induce 2174 cancers and 1011 cancer deaths.

These calculations, like all estimated health effects of radiation exposure, are based on several assumptions. When comparing digital mammography with PEM, 2 conclusions become clear: Many more cancers are induced by PEM than by digital mammography; and for both modalities, adding annual screening from age 40 to 49 roughly doubles the number of induced cancers. In a benefit-risk calculation performed for digital mammography but not for PEM, O'Connor et al (2010) nevertheless reported that the benefit-risk ratio of annual screening is still approximately 3 to 1 for women in their 40s, although it is much higher for women age 50 and older. Like Hendrick,[8] the authors concluded that "if molecular imaging techniques [including

PEM] are to be of value in screening for breast cancer, then the administered doses need to be substantially reduced to better match the effective doses of mammography."[10]

The American College of Radiology has assigned a relative radiation level (effective dose) of 10 to 30 mSv to PEM.[11] The College has also stated that, because of radiation dose, PEM and BSGI in their present form are not indicated for screening.

Because the use of BSGI and molecular breast imaging have been proposed for women at high risk of breast cancer, it should be noted there is controversy and speculation whether some women (e.g., those with *BRCA* variants) have heightened radiosensitivity.[12,13] If women with *BRCA* variants are more radiosensitive than the general population, the previous estimates may underestimate the risks they face from breast imaging with ionizing radiation (i.e., mammography, BSGI, molecular breast imaging, PEM, single-photon emission computed tomography, breast-specific computed tomography, and tomosynthesis; ultrasound and magnetic resonance imaging do not use radiation). More research will be needed to resolve this issue. Also, risks associated with radiation exposure will be greater for women at high risk of breast cancer (regardless of whether they are more radiosensitive) because they start screening at a younger age when the risks associated with radiation exposure are increased.

REGULATORY STATUS

In 2003, the PEM 2400 PET Scanner (PEM Technologies) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. FDA determined that this device was substantially equivalent to existing devices for "medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body."[14]

In 2009, the Naviscan PEM Flex™ Solo II™ High Resolution PET Scanner (Naviscan) was cleared for marketing by FDA through the 510(k) process for the same indication. The PEM 2400 PET Scanner was the predicate device. The newer device has been described by the manufacturer as "a high spatial resolution, small field-of-view PET imaging system specifically developed for close-range, spot, ie, limited field, imaging."

In 2013, Naviscan was acquired by Compañía Mexicana de Radiología SA,[15] which currently markets the Naviscan Solo II™ Breast PET Scanner in the United States (CMR Naviscan). FDA product code: KPS.

IV. RATIONALE

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Positron Emission Mammography

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POLICY NUMBER	MP-5.008

Summary of Evidence
For individuals who are being screened for breast cancer, have clinically localized breast cancer undergoing presurgical evaluation, or have a suspicious breast lesion on conventional breast cancer evaluation who receive PEM, the evidence includes prospective and retrospective studies as well as a meta-analysis. Relevant outcomes are overall survival, disease-specific survival, test accuracy and validity, and resource utilization. For each indication, it has not been demonstrated that PEM provides better diagnostic accuracy than the relevant comparators nor has PEM been shown to provide clinical utility. In addition, without demonstrated advantages in clinical utility, the relatively high radiation dosage associated with PEM do not favor its use given that with alternative tests administer lower doses. The evidence is insufficient to determine the effects of the technology on health outcomes.

V. DEFINITIONS Top

N/A

VI. BENEFIT VARIATIONS Top

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER Top

Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION Top

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Investigational when used to report Positron Emission Mammography (PEM); therefore, not covered:

CPT Codes®								
78999								

Covered when medically necessary:

CPT Codes ®								
77061	77062	77065	77066					

HCPCS Code	Description
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (List separately in addition to 77065 or 77066)

ICD-10-CM Diagnosis Codes	Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast

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ICD-10-CM Diagnosis Codes	Description
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C54.1	Malignant neoplasm of endometrium
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes
C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.89	Secondary malignant neoplasm of other digestive organs
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.31	Secondary malignant neoplasm of brain
C79.32	Secondary malignant neoplasm of cerebral meninges

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ICD-10-CM Diagnosis Codes	Description
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.81	Secondary malignant neoplasm of breast
C79.82	Secondary malignant neoplasm of genital organs
D05.01	Lobular carcinoma in situ of right breast
D05.02	Lobular carcinoma in situ of left breast
D05.11	Intraductal carcinoma in situ of right breast
D05.12	Intraductal carcinoma in situ of left breast
D05.81	Other specified type of carcinoma in situ of right breast
D05.82	Other specified type of carcinoma in situ of left breast
D07.0	Carcinoma in situ of endometrium
N60.01	Solitary cyst of right breast
N60.02	Solitary cyst of left breast
N62	Hypertrophy of breast
N63.0	Unspecified lump in unspecified breast
N63.10	Unspecified lump in the right breast, unspecified quadrant
N63.11	Unspecified lump in the right breast, upper outer quadrant
N63.12	Unspecified lump in the right breast, upper inner quadrant
N63.13	Unspecified lump in the right breast, lower outer quadrant
N63.14	Unspecified lump in the right breast, lower inner quadrant
N63.20	Unspecified lump in the left breast, unspecified quadrant
N63.21	Unspecified lump in the left breast, upper outer quadrant
N63.22	Unspecified lump in the left breast, upper inner quadrant
N63.23	Unspecified lump in the left breast, lower outer quadrant
N63.24	Unspecified lump in the left breast, lower inner quadrant
N63.31	Unspecified lump in axillary tail of the right breast
N63.32	Unspecified lump in axillary tail of the left breast
N63.41	Unspecified lump in right breast, subareolar
N63.42	Unspecified lump in left breast, subareolar
N64.0	Fissure and fistula of nipple
N64.3	Galactorrhea not associated with childbirth
N64.4	Mastodynia
N64.51	Induration of breast
N64.52	Nipple discharge
N64.53	Retraction of nipple
N64.59	Other signs and symptoms in breast
N64.89	Other specified disorders of breast

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ICD-10-CM Diagnosis Codes	Description
N65.0	Deformity of reconstructed breast
N65.1	Disproportion of reconstructed breast
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z86.012	Personal history of benign carcinoid tumor
Z98.82	Breast implant status

IX. REFERENCES

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X. POLICY HISTORY

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MP 5.008	**CAC 6/29/04**
	CAC 5/31/05
	CAC 1/31/06 Combined Full Field Digital Mammography with this policy
	CAC 2/27/07
	CAC 5/27/08
	CAC 5/26/09 Consensus
	CAC 5/25/2010 Consensus
	CAC 7/26/11 Minor Revision. Information on Digital Breast Tomosynthesis and Positron Emission Mammography (PEM) added to the policy; both considered investigational. An FEP variation was added. The statements regarding screening mammograms for women over 40 and the statement regarding studies for women under 40 were removed. A link to CBC preventative guidelines was added in their place.
	CAC 9/24/13 Consensus review. References updated but no changes to the policy statements. Background for Digital Breast Tomosynthesis and Positron Emission Mammography (PEM) updated. FEP variation revised.
	CAC 7/22/14 Consensus. No change to policy statements. References updated. Rationale section added.
	12/1/14 Removed the Medicare variation referencing NCD 220.4. Coding reviewed.
	1/15/2015 2015 Coding updated
	2/1/15 Administrative change. Added Medicare variation to reference Centers for Medicare and Medicaid Services (CMS) Medicare Claims Processing Manual. 100-04 Chapter 18 Section 20.2.2 Preventive and Screening Services. Screening Digital Breast Tomosynthesis. Effective with claim dates of service January 1, 2015 and later, HCPCS code 77063, "Screening Digital Breast Tomosynthesis, bilateral, must be billed in conjunction with the primary service mammogram code G0202.
	CAC 3/24/15 Minor review with focus on breast tomosynthesis. No change to policy statements. References updated. Rationale reviewed. Policy coded.
	CAC 11/24/15 Research performed regarding 10/5/15 announcement/update to the Pennsylvania State Mandate Act 148 of 1992 (Mammography Act). Coding reviewed/updated.

POLICY TITLE	MAMMOGRAPHY (INCLUDING COMPUTER AIDED DETECTION MAMMOGRAPHY AND POSITRON EMISSION MAMMOGRAPHY)
POLICY NUMBER	MP-5.008

	Admin update 1/1/17: Product variation section reformatted. Coding updated with changes effective 1/1/17.
	CAC 1/31/17 Consensus review. Policy statements unchanged. Description/Background, Regulatory Status, Rationale and Reference sections updated. Coding Reviewed/updated with 2017 CPT codes (77065, 77066).
	Admin update 10/1/17: Added new ICD 10 codes effective from 10/1/17 and deleted old ICD 10 codes.
	12/19/17 Consensus review. No change to the policy statements. Background, rationale, and references updated. Removed end dated codes G0204 and G0206; effective 1/1/18.
	Admin Update 1/19/18: Updated G0279 with revised description; effective 1/1/18.
	12/11/18 Consensus. No change to policy statements. Background and references updated. Rationale condensed.

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