Please note: This is a Draft policy.

Proposed/Draft LCDs are works in progress that are available on the Medicare Coverage Database site for public review. Proposed/Draft LCDs are not necessarily a reflection of the current policies or practices of the contractor.

Coverage Guidance

Coverage Indications, Limitations and/or Medical Necessity

Purpose of Policy

This policy does not designate specific special histochemical stains (aka special stains) and/or immunohistochemical (IHC) stains that should be used in the differential diagnosis of tissues or neoplasms because this information is readily available in textbooks and various scientific publications. This policy identifies the medically necessary criteria for the use of special stains and/or IHC stains and addresses, based on claims review, the scenarios that may be driving medically unnecessary over utilization or incorrect billing of these services including:

- Reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist; or
- Use of special stains and/or IHC stains without clinical evidence that the stain is actionable or provides the treating physician with information that changes patient management; or
- Use of stains when the diagnosis is already known based on morphologic evaluation; or
- Hematoxylin and eosin (H&E) staining is included in the billing CPT code and is not a separately billable service.

Background
Routine hematoxylin and eosin (H&E) staining is the cornerstone of tissue-based microscopic diagnosis. Thin sections of tissue are stained with H&E to visualize the tissue morphology. The hematoxylin dye stains the cell nuclei blue and the eosin dye stains other structures pink/red. H&E staining provides excellent detail required for tissue-based diagnosis and is not a separately billable service, as reimbursement for pathology services includes routine H&E staining. At least one lab has touted "acid hematoxylin" as a special stain for purposes of billing Medicare and private payers. Given that all hematoxylin stains are acidic and that this stain has not been recognized by the Biological Stain Commission, it is incorrect coding to present claims for this stain as a special stain.

Special stains are called "special" because they are dyes used to stain particular tissues, structures or pathogens such as bacteria that may not be visible by routine H&E staining. Special stains can identify whether a substance is present or absent, where the substance is located in the tissue specimen, and frequently, how many or how much of a substance is present. There are special stains to identify bacteria, yeast and fungi; for connective tissue, muscle, collagen, lipid and fibrin; for nucleic acids; and multi-purpose stains to identify basement membranes, mucins, and various other cellular constituents. Two major AHA CPT coding categories for special stains are recognized: For first is specifically for microorganisms; the second code is for all other purposes (not microorganisms) and specifically excludes detection of enzyme constituents.

IHC is a powerful tool for identifying substances and cells in tissue sections using the specificity of antigen-antibody reactions, where the antibody is linked to a colored indicator (stain) that can be seen with a microscope. More than 400 distinct antibody targets are currently available with varying sensitivity and specificity for a given target. A major use of IHC is to identify poorly differentiated malignant neoplasms (tumors) as a carcinoma, lymphoma, melanoma and sarcoma. Some IHC stains are useful in determining the primary site of a metastatic neoplasm, and others are used to guide specific therapies (e.g., Her2 IHC to determine potential response to trastuzumab).

Medical Necessity of Services Performed

There are many different relationships that exist in providing the provision of pathology services in the United States. Some physicians, groups, laboratories and hospitals submit global claims for services described in this policy and another entity for the technical services, it is the obligation of each entity to independently assure the medical necessity of the services rendered and billed.

Special Stains/IHC Medical Necessity

The IOM, Benefit Policy Manual (CPT15, §80.6.5) specifies “…there may be additional tests, such as special stains, that the pathologist may need to perform, even though they have not been specifically requested by the treating physician/practitioner. The pathologist may perform such additional tests under the following circumstances:

- Services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner;
- Results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; and
- Pathologist documents in his/her report why additional testing was done.”

The above citation means that reflex templates or pre-orders for special stains and/or IHC stains prior to review of the routine hematoxylin and eosin (H&E) stain by the pathologist are not reasonable and necessary. A pathologist must first review the H&E stain prior to ordering special stains or IHC. The medical necessity for the special stain or IHC studies, the results of the stain or IHC, and review of the control must be documented in the surgical pathology report.

IHC for Breast Pathology

The clinical care of patients with breast cancer depends upon the accurate diagnosis and the assessment of biomarkers. Hormone receptor assays and Her2 testing are recommended on all primary invasive breast cancers, and on recurrent or metastatic cancers. At the current time, there is no recommendation for Her2 testing on in situ breast lesions outside of a clinical trial. While there are a number of promising additional biomarkers, such as Ki-67, PI3K and gene expression assays, the College of American Pathologists (CAP), the American Society of Clinical Oncologist (ASCO) and the National Comprehensive Cancer Network (NCCN) have not recognized these markers in patient treatment pathways.

Estrogen receptor (ER), progesterone receptor (PR) and epidermal growth factor receptor 2 (Her2) are well-established prognostic markers in breast cancer management. The triple negative breast carcinoma subtype (ER-/PR-/Her2-) has been associated with worse overall prognosis in comparison with other subtypes in breast lesions outside of a clinical trial. While there are a number of promising additional biomarkers, such as Ki-67, PK3 and gene expression assays, the College of American Pathologists (CAP), the American Society of Clinical Oncologist (ASCO) and the National Comprehensive Cancer Network (NCCN) have not recognized these markers in patient treatment pathways.

Ki-67 expression is a biomarker for proliferation and has been associated with response to therapy, but methods of measurement are controversial. In December, 2013, the CAP reported that there is a lack of consensus on scoring, definition of low versus high expression, an appropriate cut point for positivity, or which part of the tumor should be scored, (e.g., leading edge, hot spots, overall average). There is also a paucity of the effects of pre-analytical variables (e.g., ischemic time, length of fixation, antigen retrieval) on Ki-67 staining. For these reasons, routine testing of breast cancers for Ki-67 expression is not currently recommended by either ASCO or NCCN.

The clinical utility of testing for hormone receptors in in-situ breast cancer differs from those of invasive disease. Guidelines and the peer reviewed literature support the use of ER testing for in-situ breast neoplasia and PR testing only when the ER status is negative (Lester, personal communication). Clinical guidelines have not been established for the use of Her2 or other biomarkers in patients with non-invasive breast neoplasia.

In the absence of professional guidelines based on proven scientific literature, standing orders from clinicians for tests as Ki-67 and EGFR on every breast cancer are not reasonable and necessary, and are not a covered Medicine service.

In addition, basal phenotype markers (e.g. IHC for CK5) is not routinely necessary. Neither are IHC stains such as E-cadherin, p27, or high molecular weight cytokeratin to distinguish ductal from lobular differentiation necessary on every breast case, nor are myoepithelial cell markers such as p63 or smooth muscle myosin heavy chain necessary on every case.

Special Stains and/or IHC for GI Pathology

Pathologists are often called upon to microscopically diagnose abnormalities seen on endoscopic exam of the esophagus, stomach, duodenum and colon. Biopsy specimens constitute an important diagnostic patient service. Most normal and abnormal conditions of these organs can be detected by the use of routine H&E stain. Ordering special stains or IHC stains prior to review of the routine H&E stain is not reasonable and necessary. For most esophageal, gastric and duodenal specimens, it is not reasonable or necessary to perform special stains such as Cx2 or to determine if clinically meaningful intestinal metaplasia is present. In addition, it is not usually reasonable and necessary to perform special stains or IHC to determine the presence of H. pylori organisms.

Other examples of special stains or IHC that are not reasonable and necessary on every specimen include:

- Esophagus – fungal stains, trichrome, DPAS, CDX-2 or other mucin stains
- Duodenum – AB-PAS, D-PAS, CDX-2 or other mucin stains, or special stains or IHC for H pylori, or neuroendocrine markers such as synaptophysin or chromogranin
- Duodenum – AB-PAS, D-PAS, CD3, and trichrome, or other mucin stains
- Colon – CD3, p53 trichrome
- Hyperplastic polyps – Ki67, CK20, p53, CEA, BRAF
- Tubular or tubulovillous adenoma – Ki-67, CK20, CEA, p53, MMIR

If special stains or IHC are needed in addition to the routine H&E for gastric specimens, specific documentation to justify the medical necessity for the stain is required in the pathology report. Cases that may require special stains or IHC include but are not limited to the following:

- Detection of H pylori in an appropriate milieu when organisms are not seen on H&E
- Evaluating atrophic gastritis for evidence of autoimmune etiology and for enterochromaffin-like (ECL) cell hyperplasia/carcinoid tumor
- Characterizing a carcinoma, lymphoma, melanoma or sarcoma
- Defining a GIST tumor and to distinguish it from mimics

Scientific data demonstrates that the combined number of gastric biopsies requiring special stains or IHC is roughly 20% of biopsies received and examined in a pathology practice. GI specialty practices with a large GI referral base or GI consultant pathologists may sometimes exceed this relative number of special stains/IHC, but one would not expect to see routine high utilization of special stains or IHC.

Over-utilization of special stains has also been observed with duodenal biopsies where CD3 and AB/D-PAS are reportedly used to help exclude intraepithelial lymphocytosis and gastric metaplasia. Both of these conditions, if present, are easily recognizable on H&E morphology. Mucin stains such as AB/PAS or DPAS would be reasonable and necessary in limited circumstances, and rarely is CD3 warranted on duodenal biopsies which show villous architectural abnormalities.
Architectural and histologic features define colonic polyps including hyperplastic, inflammatory, and adenomatous lesions. Special stains and/or IHC stains are not reasonable and necessary for colonic polyps despite text books noting, for example, thickened subepithelial collagen demonstrated by trichrome or collagen staining in hyperplastic polyps, or carcinoembryonic antigen (CEA) overexpression in hyperplastic polyps. While the information is of academic interest, special stains are not reasonable and necessary to make the diagnosis of various colonic polyps.

Lynch Syndrome tumor screening for DNA mismatch repair (MLH1, MSH2, MSH6 and PMS2) by qualitative IHC and/or microsatellite instability (MSI) is considered medically necessary and covered by Medicare for the following indications:

- All individuals with colorectal cancer diagnosed at age ≥70 years of age, and those > 70 years of age who meet the revised Bethesda guidelines OR
- Individuals with endometrial cancer

No definitive algorithm for LS screening has been recommended. However, if IHC is done first and is abnormal, MSI testing is not warranted. If IHC is normal, MSI may be warranted.

**Special Stains and/or IHC for Prostate Pathology**

The accuracy of the pathologic diagnosis of prostate cancer is critical for optimal patient care. The diagnosis can usually be made on morphologic features such as growth pattern, nuclear atypia and the absence of basal cells. However, it may be difficult to reach a firm diagnosis by routine H&E stain for small foci of cancer in needle biopsies because many benign conditions can mimic prostate cancer.

The immunohistochemical diagnosis of prostate cancer largely depends on panels of markers because no absolutely specific and sensitive marker for prostate cancer has yet been identified. These panels usually include at least one basal cell marker, such as high-molecular-weight cytokeratin (HMWCK) or p63, and the prostate cancer-specific marker, alpha-methyl-CoA-Racemase (AMACR). Although AMACR is considered a useful IHC marker for prostate cancer, because of non-standardized immunostaining protocols, interpretation criteria and heterogeneous staining pattern, there is wide variation in the sensitivity and specificity of AMACR immunoreactivity in prostate biopsies. Furthermore, because AMACR expression has been demonstrated in high-grade PIN, atypical adenomatous hyperplasia/adenosis and nephrogenic adenoma, it is recommended that AMACR is best restricted to the evaluation of morphologically highly suspicious foci in which negative immunoreactivity of basal cell markers alone is insufficient to establish a diagnosis of cancer.

PTEN and MYC may provide some prognostic information but neither is part of any standard treatment protocol and neither should be routinely performed. ERG is another IHC that is more likely to be positive in cancer than in benign tissue, but it does not add information to conventional PIN4 testing. Similarly, neuroendocrine markers, such as IHC for synaptophysin, may be indicated in cases of recurrent/metastatic prostate carcinoma that have undergone small cell transformation after hormone therapy. The latter marker is only necessary for high grade, undifferentiated tumors and should not be used routinely.

PIN4 is an IHC cocktail of CK5/14, p63 and P504S that is used primarily to differentiate normal and neoplastic epithelial tissues. In prostate tissue, CK5 and CK14 are detected in basal cells of normal glands and prostatic intraepithelial neoplasia (PIN) which is a precursor lesion to prostatic adenocarcinoma. However, expression of CK5 and CK14 is not identified in invasive prostatic adenocarcinoma. P63 is detected in nuclei of basal epithelium in normal prostate glands, but is not expressed in malignant prostate tumors. Because P504S (aka AMACR) is not specific for prostatic adenocarcinoma, the use of PIN4 is best restricted to evaluation of morphologically highly suspicious foci.

It is not necessary and the IHC panels may be necessary only for IHC testing (either single antibody or antibody cocktails) on cases with morphologically negative cores. It is not reasonable and necessary to request a panel for IHC testing in a negative or a suspicious core biopsy when obvious prostate cancer is present in other cores. While the pathologist may choose to confirm a suspicious focus in one or more cores in a case where the diagnosis of cancer has already been made, it is not a Medicare covered service because it provides no additional actionable information to the treating physician.

Prostate cases that may require reasonable and necessary IHC staining include but are not limited to the following:

- Indeterminate/suspicious focus and no other cores are positive for cancer;
- Single worrisome core with minimal % tumor (roughly <5%);
- Single worrisome core contralateral to a positive core(s) unless the patient is to be treated with unilateral XRT. Billing for IHC on the contralateral side to a positive prostate cancer diagnosis is not reasonable and necessary;
- Identify tumor invasion of adjacent structures;
- Determine origin of undifferentiated/poorly differentiated neoplasm, such as bladder vs prostate;
- Other unexpected results when specific cell stains would be necessary

The International Society of Pathology (ISUP) recommendations state that at the current time, there are no prognostic IHC or molecular studies that are recommended to be routinely performed on biopsy or resection specimens.

The surgical pathology report is expected to designate the specific block(s) upon which IHC testing is performed, the reason for IHC testing, the specific markers, and the cases for which IHC is not appropriate. It is not reasonable and necessary to order IHC testing (either single antibody or antibody cocktails) on cases with morphologically negative cores. It is not reasonable and necessary to request IHC testing in a negative or a suspicious core biopsy when obvious prostate cancer is present in other cores. While the pathologist may choose to confirm a suspicious focus in one or more cores in a case where the diagnosis of cancer has already been made, it is not a Medicare covered service because it provides no additional actionable information to the treating physician.

**Special Stains and/or IHC for Lung Cancer**

The diagnostic challenge of a lung biopsy can often prompt the need for additional stains to define the neoplasm. Two important considerations need to be considered in this regard:

- The diagnosis of squamous cell cancer can often be made without the use of any special stains, and
- The diagnosis of non-small cell carcinoma often requires additional stains but it is essential that tumor tissue be carefully triaged to allow the patient’s sample to be tested for molecular markers (EGFR, ALK, and others) when clinically indicated.

Experts in pulmonary pathology recommend starting the evaluation of non-small cell carcinomas with a combination of TTF-1 and p40 or p63 IHCs. Often these two stains are all that are needed to come to a reasonable diagnosis and retain enough tumor sample to complete molecular studies. In rare patients, a few additional IHCs or mucin stains may be needed.

**KI-67/MIB-1**

KI-67 and MIB-1 monoclonal antibodies are directed against different epitopes of the same proliferation-related antigen. These stains are used to determine the proliferative rate of a tumor. KI-67 antigen or protein (hereafter KI-67) is present during all active phases of the cell cycle (G1, S, G2, and mitosis), but is absent from resting cells (G0). By measuring the amount of tumor cells expressing Ki-67, an estimate of DNA synthesis can be determined which has been found comparable to a mitotic count performed on a standard H&E slide. Furthermore, KI-67/MIB-1 antibodies have suffered from a lack of international standardization which has limited their clinical usefulness. This is noted above in the discussion of breast cancers.

**Classification of lung neuroendocrine (NE) tumors**

Lung neuroendocrine tumors (NETs) include small cell lung carcinoma (SCLC) in surgical specimens. Multiple challenges exist with the characterization of the KI-67 labeling index because of variables in obtaining the numerator and denominator of the index fraction. Its diagnostic role has not been ascertained. Although KI-67 is a technically straightforward IHC stain, it is not a cost-effective marker for small cell lung carcinoma. It is not reasonable and necessary to use KI-67 in small cell lung carcinoma.

While KI-67 has been studied in lung neuroendocrine tumors, the clinical implications of KI-67 are not clear. KI-67 staining is the most frequently used in the differential diagnosis of TC and AC from SCLC in non-surgical specimens. Multiple challenges exist with the characterization of the KI-67 labeling index because of variables in obtaining the numerator and denominator of the index fraction. Its diagnostic role has not been ascertained. Although KI-67 is a technically straightforward IHC stain, it is not a cost-effective marker for small cell lung carcinoma.

**Ki-67 by IHC**

Ki-67 has clinical utility in the workup of lymphomas (Banks, personal communication). Ki-67 has several established applications including:

- Final confirmation for the diagnosis of any low-grade lymphoma. A number of publications show a worse prognosis for follicular lymphomas which appear to be grade 1 or 2 but demonstrate high Ki-67 labeling. Similarly, small lymphocytic lymphomas/CLL with a high proliferative rate (“prolymphocytic progression”) may be best detected with Ki-67
- Distinguishing higher versus lower grade mantle cell lymphoma. A small percentage of cases behave as low grade rather than intermediate grade, and Ki-67 is the most accurate means to detect this subgroup. In addition, distinguishing the highly aggressive blasticoid variant is aided by Ki-67 IHC testing.

https://coverage.cms.gov/index presuming LCD Number is 35692& LCD
IHC for Chemosensitivity and Resistance Tumor Profiling

ER, PR, and Her2 hormonal receptor status have demonstrated clinical utility in invasive breast cancer, as well as ER, and PR when appropriate, for in-situ breast cancer. ER and PR are performed by IHC specifically for tamoxifen therapy. Her2 testing has proven clinical utility in esophago-gastric and gastric cancers to determine response to trastuzumab. ER, PR and Her2 testing for the purpose of identifying patients likely to respond to hormonal therapy, biologics or chemotherapy is a covered Medicare service when medically necessary for breast and gastric adenocarcinoma.

Similarly, the efficacy of imatinib, a CD117 inhibitor, is determined by the mutation status of CD117 expression (c-KIT mutation). CD117 by IHC has a proven clinical benefit in gastrointestinal stromal tumors (GIST), some advanced dermatofibrosarcoma protubersans (DFSP), some lymphohistiocytic and myeloid leukemias, and mast cell tumors, and is a covered Medicare service when medically necessary.

However, IHC testing as above is distinctly different from chemotherapy sensitivity and/or resistance testing profiles offered by some labs to assist physicians in their selection of specific chemotherapeutic agents based on IHC antigen or protein expression in individual tumors. The goal stated by these profiles is to select a drug or combination of drugs from a panel of drugs to which a tumor has greater expression, and to avoid drugs to which the tumor has less expression.

Neither the ASCO nor the NCCN has endorsed chemosensitivity tumor profile testing by IHC. ASCO has stated, "the use of CSRA’s (chemosensitivity and resistance assays) to select chemotherapeutic agents for individual patients is not recommended outside of the clinical trial setting." While the NCCN's Guidelines for Ovarian Cancer (V3.2014) states "chemosensitivity/resistance and/or other biomarker assays are being used in some NCCN member institutions for decisions related to future chemotherapy in situations where there are multiple equivalent chemotherapy options available. The current level of evidence is not sufficient (Category 3) to supplant standard of care chemotherapy." The NCCN panel also stated that in vitro chemosensitivity testing is choose a chemotherapy regimen for recurrent disease should not be recommended due to lack of demonstrated efficacy. Such IHC panels include but are not limited to the following biomarkers for specific drugs:

- ALK for crizotinib, penetratin
- Androgen receptor (AR) for goserelin, leuprolide, gonadorelin, flutamide, bicalutamide, abiraterone, enzalutamide;
- Androgen receptor receptor for bicalutamide, flutamide, abiraterone and enzalutamide;
- AREG for cetuximab, panitumumab
- BRAF for vemurafenib and dabrafenib
- BRCA1 for cisplatin, carboplatin
- cKIT for sorafenib, sunitinib, imatinib
- cMET for erlotinib, gefitinib
- EGFR for gefitinib, panitumumab, erlotinib, cetuximab, FOLR1-EGFR
- EGFRVIII, GNA11, GNAQ, IDH2 – for clinical trials
- ER and PR for tamoxifen, goserelin, toremifene, fulvestrant, letrozole, anastrozole, exemestane, megestrol acetate, erlotinib, panitumumab, medroxyprogesterone;
- ERO2 for oxaliplatin, cisplatin, carboplatin, CAPOX, FOLFOX
- EREG for cetuximab, panitumumab
- HER2 (EnB2), PGP and TOP2A (topoisomerase IIa) for doxorubicin, liposomal doxorubicin, epirubicin;
- HER2 or lablibin; epirubicin, pertuzumab, trastuzumab, liposomal doxorubicin, doxorubicin, Kras for panitumumab, cetuximab, gefitinib, erlotinib, sunitinib
- MGMT for temozolomide and dacarbazine
- MRPI for vinorelbine, vincristine, doxorubicin, epirubicin, vinblastine, methotrexate
- NRAS for cetuximab, panitumumab
- PDGFR for imatinib
- PGP (aka MDR1 and ABCB1) for doxorubicin, vincristine, vinblastine, etoposide, liposomal doxorubicin, paclitaxel, docetaxel, vinorelbine, epirubicin;
- PIK3CA for lapatinib, panitumumab, trastuzumab, cetuximab, temsirolimus
- PTEN for gefitinib, cetuximab, erlotinib, trastuzumab, panitumumab, everolimus, temsirolimus
- RET for vandetanib
- ROS1 for crizotinib
- RRMM for gemcitabine;
- SPARC (monoclonal and polyclonal) for nab-paclitaxel;
- TLE3, TUBB3 for docetaxel, paclitaxel;
- TOPO1 for irinotecan, topotecan, FOLFI;
- TS (thymidylate synthase or TYMS) for fluorouracil, capecitabine and pemetrexed

Chemosensitivity profile tumor panels, regardless of whether it is performed by IHC or chromogenic in-situ hybridization (CISH), is not reasonable and necessary for the reasons cited above, and is not a Medicare covered service.

Note, some of these markers are legitimate biomarkers for specified drugs when performed by mutation analysis or FISH testing.

IHC for Cervical/Gyn/Bladder/Kidney Tumors

A variety of IHC stains have found limited use in cervical, gynecologic, and urologic tumor settings. In unusual cases of cervical dysplasia, markers or surrogate markers for HPV may be useful where the diagnosis on conventional H&E stain cannot be made with certainty. These markers are clearly not necessary and reasonable for the reasons cited above, and is not a Medicare covered service.

IHC for Skin & Cutaneous/Soft Tissue/CNS & Peripheral Nervous System Lesions

It is well recognized that most skin lesions are diagnosed with routine H&E slides. That is the case for most melanomas and other pigmented lesions as well. A minority of skin lesions require immunostains (e.g., atypical fibroxanthomas, Merkel cell lesions, lymphomas). Most common skin lesions (e.g., seborrheic keratosis) do not require IHC stains. Use of IHC morphometric codes for skin lesions is incorrect coding.

Similarly, most soft tissue lesions do not require IHC stains or other "special" stains. Soft tissue masses may require stains (e.g., smooth muscle differentiation in a malignant mass) but the most do not.

Many CNS and peripheral nervous system lesions are read routinely by IHC. It is unusual for a meningioma to require an IHC stain. The primary role of IHC for CNS and peripheral nervous system lesions is to differentiate primary lesions from metastatic lesions.

IHC for Bone Marrow Samples

Most bone marrow samples are diagnosed with the use of Wright's stained smears and the use of H&E stained slides with an iron stain supplementing the battery. The use of IHC stains may assist in the interpretation of cases where flow cytometry does not fit with the routine slide interpretation or when flow cytometry was not obtained. IHC stains are not needed to confirm the results of flow and cytogenetic studies. Specifically, it is not reasonable and necessary to perform the same marker (e.g. CD20) by flow and by IHC on the same case, as the information is duplicative and does not provide additional actionable information. Thus the duplicate testing is not a Medicare covered service.
Proposed/Draft Process Information

- Associated Information
  N/A

- Sources of Information and Basis for Decision

- References

  2. Banks, PM. Ventana Medical Systems, Tucson AZ, personal communication.
  12. Lester, S. Brigham and Women’s, Boston, MA, personal communication

Open Meetings/Part B MAC Contractor Advisory Committee (CAC) Meetings

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- Coding Information

[PROPOSED/DRAFT]

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes
Group 1 Paragraph: N/A

Group 1 Codes:
- 88360: MORPHOMETRIC ANALYSIS, TUMOR IMMUNOHISTOCHEMISTRY (EG, HER-2/NEU, ESTROGEN RECEPTOR/PROGESTERONE RECEPTOR), QUANTITATIVE OR SEMIQUANTITATIVE, EACH ANTIBODY; MANUAL
- 88361: MORPHOMETRIC ANALYSIS, TUMOR IMMUNOHISTOCHEMISTRY (EG, HER-2/NEU, ESTROGEN RECEPTOR/PROGESTERONE RECEPTOR), QUANTITATIVE OR SEMIQUANTITATIVE, EACH ANTIBODY; USING COMPUTER-ASSISTED TECHNOLOGY

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ICD-9 Codes that Support Medical Necessity

Group 1 Paragraph: N/A

Group 1 Codes:
- 041.86 HELICOBACTER PYLORI [H. PYLORI]

Group 1 Asterisk: N/A

ICD-9 Codes that DO NOT Support Medical Necessity

- Associated Documents
  - Attachments
    - N/A
  - Related Local Coverage Documents
    - N/A
  - Related National Coverage Documents
    - N/A
  - All Versions
    - Updated on 10/22/2014 with effective dates N/A - N/A

- Keywords
  - N/A