Immunohistochemistry (IHC)

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Procedures addressed

The inclusion of any procedure code in this table does not imply that the code is under management or requires prior authorization. Refer to the specific Health Plan's procedure code list for management requirements.

Procedures addressed by this guideline	Procedure codes
Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure)	88341
Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure	88342
Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure	88344

Criteria

This guideline addresses immunohistochemistry (IHC)-based tests using CPT codes 88341-88344. It is not intended to encompass immunohistochemistry-based tests billed using more specific CPT codes (e.g., 88360, 88361).

Medical necessity requirements

In general, IHC in pathology practice should be used to complement, rather than substitute for, morphologic examination on routine H&E staining. Given the numerous applications of IHC, it is not practical to address all uses. However, it is possible to determine a maximum number of stains that should be reasonable for the vast majority of applications, and an approximate frequency by which the maximum threshold would be reached based on historical practice trends in various settings, guidelines, and published studies.

Most immunohistochemistry applications, when medically necessary, should rarely require more than 7 IHC stains per unique specimen. Therefore, the following criteria will be applied when processing claims for IHC procedures:

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- In addition to the first IHC stain billed with one unit of 88342, medical necessity will routinely be limited to 6 units of CPT 88341 per specimen in which malignancy is present. Exceptions will be considered on a case by case basis.
- Immunohistochemistry is not medically necessary when performed on histologic lesions for which a diagnosis is readily made based on cytologic and architectural features seen on routine H&E staining. Examples include seborrheic keratosis, junctional and compound nevi, hyperplastic polyps and adenomas, and basal cell and squamous cell carcinoma of skin, among others.
- Immunohistochemistry for the evaluation of Barrett's esophagus (intestinal metaplasia) or Barrett's dysplasia in esophageal biopsies is not medically necessary.
- Immunohistochemistry for assessing intraepithelial lymphocytosis in assessing the presence of celiac disease in duodenal or small intestinal biopsies is not medically necessary, except in cases of refractory celiac disease or when routine histologic findings and serologic studies are inconsistent.
- Immunohistochemistry to assess the presence of Helicobacter pylori in gastric biopsies is not medically necessary, except when the pathology report includes the following required documentation:
    - the clinical indication for the IHC stain
    - a statement indicating that Helicobacter type organisms are not detectable on the H&E stained slide, AND
    - The pathology report indicates the presence of one of the following:
        - Chemical gastropathy with superimposed chronic gastritis
        - Chronic inactive gastritis, active gastritis, or carditis
        - Ulceration, lymphoma, or adenocarcinoma
        - Lymphocytic gastritis

Immunohistochemistry performed on prostate biopsies is not medically necessary in the following circumstances:

- Histologically benign tissue cores or cores with readily identifiable carcinoma on H&E slides
- Cores suspicious for Gleason score 3+3=6 cancer when at least one other core contains a Gleason score 3+4=7 or higher
- Cores containing atypical glandular morphology or foci suspicious for intraductal carcinoma when at least one other core contains a Gleason score 4+3=7 or higher

Immunohistochemistry and flow cytometry generally should not be performed for the same or similar specimens obtained as a result of the same clinical episode, and only one of these methods should be necessary to establish a diagnosis.

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Any claim for CPT 88341-88344, regardless of the number of units billed, may be subject to post-service medical necessity review if medically unnecessary or excess units are suggested based on the available clinical information.

Billing and Reimbursement

This section outlines the billing requirements for tests addressed in this guideline. These requirements will be enforced during the case review process whenever appropriate. Examples of requirements may include specific coding scenarios, limits on allowable test combinations or frequency and/or information that must be provided on a claim for automated processing. Any claims submitted without the necessary information to allow for automated processing (e.g. ICD code, place of service, etc.) will not be reimbursable as billed. Any claim may require submission of medical records for post service review.

Immunohistochemistry is generally not necessary for the diagnosis of most skin lesions. When the claim includes any one of the following ICD codes: C44.X, D03.X, D04.X, D22.X, D23.X, D48.5, L57.0, L82.X, it will not be reimbursable without supporting documentation demonstrating medical necessity and a record review by a medical director.

Claims for immunohistochemistry (CPT 88341-88344) and flow cytometry (CPT codes 88184-88189) on the same or similar specimens or on the same date of service will be subject to post-service medical necessity review.

There are currently three codes for reporting qualitative IHC stains: 88341, 88342, and 88344. IHC stains are now reported per unique specimen instead of per block (paraffin-embedded tissue). An example of unique specimens that may be evaluated on the same date of service is separate, histologically distinct lung neoplasms in different lung lobes.

Current codes:

- Codes 88342 and 88341 are reported for a single antibody stain procedure.
- Code 88344 is used to report a multiplex staining procedure* (e.g., PIN-4, ADH-5, Uro-3 triple stain).

Retired codes:

- Code 88343 was deleted in 2015.
- The HCPCS codes G0461 and G0462 are also no longer reportable.

*Multiplex staining refers to the use of two or more different antibodies mixed together (“cocktails”) that demonstrate different staining characteristics on a single slide. Multiplex does not refer to antibody cocktails such as Cytokeratin AE1/AE3 that do not show distinct color changes between antibodies. There are a limited, although expanding, number of multiplex stains with PIN4 being among the most frequently utilized (evaluation of prostate biopsies).[4]

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The following limitations will be applied when processing claims for IHC procedures:

- Qualitative immunohistochemistry procedure codes 88341-88344 should only be used when other, more specific, procedure codes are not available to describe the performed test, AND
- For single antibody stains:
    - One unit of 88342 should be used for the first single antibody applied to a unique specimen. Additional stains applied to that same specimen are billed with one unit of 88341 per stain. CPT 88341 should therefore not be billed without 88342 on the same date of service, and
    - No more than one unit of 88342 is routinely reimbursable on a single date of service. Units over 1 per date of service are subject to post service review. Units in excess of 6 per DOS billed for 88341 are subject to post service review. In particular, reimbursement will routinely be limited to 6 units of CPT 88341 per specimen in which malignancy is present, indicated on the claim by the inclusion of an ICD code from C00.X-C41.X, C43.X, or C45.X--C96.X, and
    - When more than one specimen is studied, the units of 88341 applicable to each unique specimen should be entered separately on the claim and each entry should have a corresponding unit of 88342 billed.
- For multiplex antibody stains:
    - One unit of 88344 may be used for a multiplex stain applied to a unique specimen. A multiplex stain is defined as a combination of antibodies that yield separately identifiable staining characteristics on a single slide, and
    - No more than one multiplex stain on one specimen should be necessary on a single date of service. Units over one per DOS are subject to post service review, and
    - Modifiers 26 and TC can be used to split codes 88341, 88342, and 88344 into their technical and professional components. When split, one unit of the technical component of a code and one unit of the professional component of a code will be viewed as the equivalent of one unit when calculating maximum allowable units for any code. Alternatively, the sum of units billed with the same modifier (e.g. TC) can fulfill the maximum allowable units regardless of whether the units for the other modifier (e.g., 26) are ever billed

What is immunohistochemistry?

Definition

Immunohistochemistry (IHC) is a method used to determine the expression of biomarkers in tissue. Antibodies that detect specific antigens are applied to tissue and attach to their target antigen. The antibodies are tagged with a visible label that allows

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the pattern or distribution of the antigen in the tissue to be directly visualized microscopically.

Test information

Immunohistochemistry is used widely in pathology for diagnosis, sub-typing, and increasingly to identify therapeutic targets. It is also used in the evaluation of cancers of unknown primary. Some of the most common uses are outlined below:[1-3]

- Diagnostic
  - Initial tumor classification (including cancers of unknown origin), and sub-typing
  - Identification of selected infectious agents (e.g. CMV)
  - Neurodegenerative disorder classification
- Therapy Selection/Management
  - Identification of specific therapeutic target expression (e.g., HER2/neu)
  - Further characterization of prognosis to gauge treatment aggressiveness
- Genetic Disorder Evaluation
  - Altered gene expression predictive of an underlying genetic disorder (e.g., loss of expression of the mismatch repair genes associated with Lynch syndrome)
  - Skeletal muscle biopsy protein abnormalities that help establish a specific muscular dystrophy diagnosis

Guidelines and evidence

Introduction

This section includes guidelines and evidence pertaining to IHC testing.

Several studies have included data on the average number of immunohistochemical (IHC) stains used per case in various settings. In a cost-effectiveness of IHC study, Raab (2000) modeled the analysis on a 5-antibody panel, which was the average number of antibodies ordered per case in that hospital system. No data was provided on the upper and lower limits of that range.[4]

A study published by Shah, et al. (2012) looked at the use of IHC stains among different pathology practice settings, which included academic, private and commercial practices. The study concluded that regardless of where IHC was performed, the average number of stains ordered per case was similar among all groups although ranges varied considerably. Pathologists from private groups performed an average of 4 stains , whereas those in commercial laboratories used an average of 3 stains per case. When broken down by organ system, the highest average was 6 stains per case

for head and neck tissue.[5] In a multi-center study comparing immunohistochemistry to gene expression profiling of cancers of unknown primary, an average of 8.3 IHC stains were performed, and in over half of the cases, 5 or fewer stains were performed.[6]

The National Comprehensive Cancer Network (NCCN) Guidelines for Treatment of Cancer by Site provide detailed guidelines on the use of individual IHC stains in the diagnosis and management of each cancer type addressed.[7]

National Comprehensive Cancer Network Guidelines on Occult Primary (Cancer of Unknown Primary [CUP]) stated the following:[8]

- "In patients with occult primary tumors, immunohistochemical studies are useful for the characterization of poorly differentiated or undifferentiated tumors and for cell-type determination and pathologic diagnosis. However, exhaustive IHC studies (in excess of 10-12 stains) have not been shown to increase the diagnostic accuracy in identifying the putative primary sites. Therefore, testing a large series of IHC markers in individual patients should be avoided." NCCN recommends a tiered approach as follows: first tier determines tissue lineage, second tier can suggest putative primary sites, and an optional third tier to identify therapeutic targets in select patients.[8]

The number of IHC stains necessary to evaluate a cancer of unknown primary can be reduced to as few as 6 by taking into account the tumor characteristics on routine evaluation by light microscopy, the pre-test probability of a diagnosis based on the tumor location, clinical features, results of imaging studies, and the sensitivity and specificity of each stain.[9-12]

Gastric biopsies

Ordering immunohistochemical staining of gastric biopsies for Helicobacter pylori prior to reviewing the routine hematoxylin and eosin (H&E) stained slide is generally unnecessary, as often times the biopsies do not demonstrate significant inflammation, or the organisms are identifiable on the H&E stained slide.[13-16] As noted by the Rodger C. Haggitt Gastrointestinal Pathology Society:[17]

- "…routine application of ancillary stains to all gastric biopsies is not justified by a perceived need to expedite the few cases in which staining might be necessary."

Ancillary studies on gastric biopsies, in the absence of detectable Helicobacter organisms on the H&E slide, may be justified by the following histologic findings:[17]

- Chemical gastropathy with superimposed chronic gastritis
- Chronic active gastritis or carditis
- Ulceration, lymphoma, or adenocarcinoma
- Lymphocytic gastritis
- Chronic inactive gastritis in patients with H. pylori treatment or duodenal lymphocytosis

Esophageal biopsies

Reflexive staining to assess the presence of goblet cell metaplasia in esophageal biopsies, in the form of special histochemical stains or immunohistochemistry, is generally unnecessary as goblet cells may be identified by routine H&E staining in most cases .[18] The Rodger C. Haggitt Gastrointestinal Pathology Society has also not recommended ancillary staining in the assessment of Barrett esophagus-associated dysplasia:[18]

- "… morphology should remain the gold standard for diagnosing BE and BE-associated dysplasia at this time. The Alcian blue stain at p=pH 2.5 combined with a PAS stain has limited utility in morphologically challenging cases of BE, particularly in the distinction of pseudogoblet cells from true goblet cells, and is not indicated as a reflexive test. Other ancillary stains need further study before they can routinely be applied to the diagnosis of BE and BE-associated dysplasia. " [BE=Barret esophagus]

Several studies have suggested that results of IHC staining for p53 can be used to assess risk of BE progression to carcinoma, however these studies have not demonstrated how such testing can alter surveillance strategies or improve health outcomes .[18,19]

Duodenal biopsies

An increase in intraepithelial lymphocytes in small intestinal villi is one histologic feature of celiac disease or gluten sensitive enteropathy (GSE). The lymphocytes in non-refractory GSE are CD3 positive, CD8 positive T-cells which may be identified by immunohistochemistry, however IHC staining may lead to an over-diagnosis of GSE, partly because of histologic mimics .[20-22] Additionally, when histologic features are normal, IHC staining for T-cell markers does not improve detection of GSE .[23] The European Society for the Study of Coeliac Disease guideline suggested that immunohistochemistry for CD3 be performed in equivocal cases.[22]

Lung cancer biopsies

The evaluation of lung biopsies containing a non-small cell lung cancer (NSCLC) requires a balance between achieving an accurate tumor classification and preserving sufficient tissue for molecular studies that may direct therapy. In the interest of achieving a diagnosis of NSCLC while allowing sufficient tissue for ancillary studies, the International Association for the Study of Lung Cancer/American Thoracic Society/ European Respiratory Society stated:[24]

- "Methods that use substantial amounts of tissue to differentiate adenocarcinoma from squamous cell carcinoma, such as large panels of immunohistochemical stains, do not necessarily provide an advantage over routine light microscopy with a limited immunohistochemical workup."
- "In those cases where a specimen shows NSCLC lacking either definite squamous or adenocarcinoma morphology, immunohistochemistry may refine diagnosis. To

preserve as much tissue as possible for molecular testing in small biopsies, the workup should be as limited as possible. Realizing that new markers are likely to be developed, we suggest the initial evaluation use only one adenocarcinoma marker and one squamous marker."

In one tertiary center study of small biopsies containing lung carcinoma , a diagnosis based on histology alone was achieved in 47% of cases; the majority of the remaining cases were classified using a 3 or fewer immunohistochemical stains .[25] Separate studies determined that the majority of NSCLC cases could be classified using a panel of only 4 immunohistochemical markers .[26,27] Subsequently, the International Association for the Study of Lung Cancer (IASLC) made the following best practice recommendation of using fewer IHC stains:[28]

- "When IHC is needed for the subtyping of non-small cell carcinoma (NSCC), TTF1 and p40 are the gold standard, and these two markers are usually sufficient in clinical practice if there are no morphological features of neuroendocrine differentiation (NE)."

Prostate biopsies

In cases where prostatic carcinoma is readily identifiable on a prostate biopsy, morphologic features, growth pattern, nuclear atypia, and the absence of a basal cell layer are usually sufficient to establish a diagnosis. Because of histologic mimics, the diagnosis of small foci of prostatic carcinoma, however, may be challenging without the aid of immunohistochemical stains. These are usually performed as multiple single stains or as immunohistochemical "cocktails". In addressing the use of immunohistochemical stains on prostate specimens, the International Society of Urologic Pathologists (ISUP) has made the following recommendations:[29]

- "In the setting of obvious carcinoma or benign glands, there is no justification to do basal cell stains and AMACR. If there is a Gleason score of 3+4=7 or a higher-grade cancer on at least 1 part, the workup of other parts with an atypical focus suspicious for Gleason score 3+3=6 cancer is not recommended."
- "In the setting of Gleason score 4+3 or higher-grade cancer on at least 1 part, given that intraductal carcinoma in the vast majority of cases is considered extension of high-grade cancer into prostatic ducts and acini, it is not recommended in the setting of definitive invasive high-grade cancer that workup of additional cribriform lesions be pursued."

Biopsies of HPV-associated lower anogenital squamous lesions

The College of American Pathologists (CAP) and American Society for Colposcopy and Cervical Pathology (ASCCP) published consensus guidelines on standardization of terminology and management of HPV-associated lesions.[30] The final recommendations included detailing "the appropriate use of specific biomarkers to clarify histologic interpretations and enhance diagnostic accuracy." Regarding the use of p16

immunohistochemistry as a biomarker for biopsies of HPV-associated lower anogenital squamous lesions, the guidelines include these recommendations:

- p16 IHC is recommended when the differential diagnosis based on morphologic interpretation on H & E staining includes - IN 2.
- p16 IHC is recommended "as an adjunct to morphologic assessment for biopsy specimens interpreted as < –IN 1 that are at high risk for missed high-grade disease, which is defined as a prior cytologic interpretation of HSIL, ASC-H, ASC-US/HPV16+, or AGC (NOS)."
- p16 IHC is not recommended "as a routine adjunct to histologic assessment of biopsy specimens with morphologic interpretations of negative, –IN 1, and –IN 3."

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