Special Stains



Effective Date: 01/01/2024 Revision Date: N/A Review Date: 12/12/2023 Policy Number: WI.PA-1260 Line of Business: Medicare

Medicare Advantage Medical Coverage Policy

Table of Contents

Related Medicare Advantage Medical/Pharmacy Coverage Policies
Related Documents
Description
Coverage Determination
Coverage Limitations
Coding Information
References

Disclaimer

Change Summary

The Coverage Summaries are reviewed by the iCare Medicare Utilization Management Committee. Policies in this document may be modified by a member's coverage document. Clinical policy is not intended to preempt the judgment of the reviewing medical director or dictate to health care providers how to practice medicine. Health care providers are expected to exercise their medical judgment in rendering appropriate care. Identification of selected brand names of devices, tests and procedures in a medical coverage policy is for reference only and is not an endorsement of any one device, test, or procedure over another. Clinical technology is constantly evolving, and we reserve the right to review and update this policy periodically. References to CPT® codes or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee of claims payment. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any shape or form or by any means, electronic, mechanical, photocopying or otherwise, without permission from iCare.

Related Medicare Advantage Medical/Pharmacy Coverage Policies

None

Related Documents

Please refer to CMS website for the most current applicable CMS Online Manual System (IOMs)/National Coverage Determination (NCD)/ Local Coverage Determination (LCD)/Local Coverage Article (LCA)/ Transmittals.

Туре	Title	ID Number	Jurisdiction Medicare Administrative Contractors	Applicable States/Territor ies
			(MACs)	

Internet- Only Manuals (IOMs)	100-02 Medicare Benefit Policy Manual, Chapter 15 – Covered Medical and Other Health Services	§80.6.5 - Surgical/Cytopathology Exception		
Medicare Manual	Medicare National Correct Coding Initiative (NCCI) Policy Manual	Medicare NCCI Policy Manual		
LCD LCA	Lab: Special Histochemical Stains and Immunohistochemical Stains	<u>L36805</u> <u>A57733</u>	J5 – J8 Wisconsin Physicians Service Insurance Corporation	IA, KS, MO, NE, IN, MI
LCD LCA	Special Histochemical Stains and Immunohistochemical Stains	<u>L35986</u> <u>A59292</u>	J15 - CGS Administrators, LLC (Part A/B MAC)	кү, он
LCD LCA	Lab: Special Histochemical Stains and Immunohistochemical Stains	<u>L36351</u> <u>A57611</u>	JE - Noridian Healthcare Solutions, LLC	CA, HI, NV, American Samoa, Guam, Northern Mariana Islands
LCD LCA	Lab: Special Histochemical Stains and Immunohistochemical Stains	<u>L36353</u> <u>A57614</u>	JF - Noridian Healthcare Solutions, LLC	AK, AZ, ID, MT, ND, OR, SD, UT, WA, WY
LCD LCA	Lab: Special Histochemical Stains and Immunohistochemical Stains	<u>L35922</u> <u>A56838</u>	JJ – JM Palmetto GBA (Part A/B MAC)	AL, GA, TN NC, SC, VA, WV

Description

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. Hematoxylin dye stains the cell nuclei blue and the eosin dye stains other structures pink/red.

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 nuclei acids; and multi-purpose stains to identify basement membranes, mucins, and various other cellular constituents. Two major categories for special stains are recognized: One is specifically for microorganisms; the second is for all other purposes (not microorganisms) and specifically excludes detection of enzyme constituents.

Immunohistochemistry (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.

Morphometric analysis is a laboratory test is performed to analyze the morphometric characteristics of tumor cells using immunohistochemistry (IHC). Morphometric analysis may include a study of the size, shape, and features of the cell and nucleus, a determination of the nucleus/cytoplasm ratio, and specific DNA/RNA markers.

Coverage Determination

iCare follows the CMS requirements that only allows coverage and payment for services that are reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member except as specifically allowed by Medicare.

Please refer to the following CMS sources for guidance regarding **special stains**:

- Medicare Benefit Policy Manual, Chapter 15 Covered Medical and Other Health Services, Section 80.6.5 - Surgical/Cytopathology Exception
- Medicare NCCI Policy Manual

In interpreting or supplementing the criteria above and in order to determine medical necessity consistently, iCare may consider the criteria contained in the following:

Special stains will be considered medically reasonable and necessary when **ALL** the following requirements are met:

 These services are medically necessary so that a complete and accurate diagnosis can be reported to the treating physician/practitioner; AND

- The results of the tests are communicated to and are used by the treating physician/practitioner in the treatment of the beneficiary; AND
- The pathologist documents in his/her report why additional testing was done.

The use of the criteria in this Medicare Advantage Medical Coverage Policy provides clinical benefits highly likely to outweigh any clinical harms. Services that do not meet the criteria above are not medically necessary and thus do not provide a clinical benefit. Medically unnecessary services carry risks of adverse outcomes and may interfere with the pursuit of other treatments which have demonstrated efficacy.

Coverage Limitations

<u>US Government Publishing Office. Electronic code of federal regulations: part 411 – 42 CFR § 411.15 - Particular services excluded from coverage</u>

The following special stains will not be considered medically reasonable and necessary:

- 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 added stains when the diagnosis is already known based on morphologic evaluation of the primary stain

H&E staining provides excellent detail required for tissue-based diagnosis and is NOT a separate service, as pathology services include routine H&E staining.

"Acid hematoxylin" is not a special stain given that all hematoxylin stains are acidic and that this stain has never been recognized by the Biological Stain Commission. It is not reasonable and necessary to claim this stain as a special stain. H&E staining is included as part of pathology services.

Coding Information

Any codes listed on this policy are for informational purposes only. Do not rely on the accuracy and inclusion of specific codes. Inclusion of a code does not guarantee coverage and/or reimbursement for a service or procedure.

CPT Codes(s)	Description	Comments
88312	Special stain including interpretation and report; Group I	
00512	for microorganisms (eg, acid fast, methenamine silver)	
00212	Special stain including interpretation and report; Group II,	
88313	all other (eg, iron, trichrome), except stain for	

Morphometric analysis, tumor immunohistochemis Her-2/neu, estrogen receptor/progesterone recept quantitative or semiquantitative, per specimen, eac antibody stain procedure; manual Morphometric analysis, tumor immunohistochemis Her-2/neu, estrogen receptor/progesterone recept quantitative or semiquantitative, per specimen, eac	ire	
Morphometric analysis, tumor immunohistochemis Her-2/neu, estrogen receptor/progesterone recept quantitative or semiquantitative, per specimen, each	nistry (eg, ptor),	
antibody stain procedure; using computer-assisted technology	eptor), each single	
CPT Category III Codes(s) Description		Comments
Codes(s) Description		Comments

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Change Summary

- 01/01/2024 New Policy.

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