



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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April 19, 2021

Tamara Syrek Jensen
Director, Coverage and Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Ms. Syrek Jensen,

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide feedback on the Center for Medicare & Medicaid Services (CMS) Transmittal 10624 from March 23, 2021 regarding the National Coverage Determination (NCD) for Next Generation Sequencing (NGS) (90.2), where the agency eliminated ICD-10 “not otherwise specified” (NOS) codes effective July 1, 2021. AMP is very concerned about the impact that this will have on access to testing, as well as the administrative burden that will be added for providers. We urge CMS to retain these ICD-10 codes in the coverage policy and rescind the March 23rd transmittal.

AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the in vitro diagnostics industry. AMP members are experts in molecular pathology, and the implementation of and coverage and payment determinations for these codes have a direct impact on their practice.

The CMS Transmittal 10624 removed a large number of ICD-10 NOS codes, which are the more general ‘unspecified’ location codes (i.e., not specifying left or right breast) from each test’s approved list of ICD-10 codes. Our members are greatly concerned that removing these codes will restrict patient access to medically appropriate NGS testing and increase the administrative burden to ensure coverage. While more specific codes for standard and usual anatomic locations (i.e., right/left breast) and gender (i.e., male breast/female breast) exist, there are a number of clinical situations in which use of the more general ‘unspecified’ location code is appropriate.

In the case of breast cancer, eliminating the more general ‘unspecified’ location codes presupposes that breast tissue and therefore breast carcinoma only exists/arises in the usual anatomic locations and ignores other possible sites for breast cancer arising in supernumerary (referenced by ICD-10 codes C50.019, C50.119, C50.219, C50.319, C50.419, C50.519, C50.619, C50.819 and C50.919 for female breast cancer and ICD C50.029, C50.129, C50.229, C50.329, C50.429, .529, C50.629, C50.829 and C50.929 for the male breast) or accessory (ectopic) breast tissue partially addressed by ICD codes C49.10 and C49.20. The incidence of carcinoma arising in ectopic breast tissue is 0.3-0.6% of all breast cancer and locations can range from axilla to chest wall, scapula

(back), thigh and genital regions^{1,2,3,4,5}. We are concerned about the effect on patients with breast and ovarian cancers as several of the ICD-10 codes for the inherited and somatic types of these cancers are designated for removal. We have identified these codes in Appendix A.

For a second example, these more general ‘unspecified’ location ICD-10 codes are appropriate for patients receiving NGS tests that are covered under the NCD, particularly in unusual cases with neoplasms of unknown primary and when samples are taken from metastatic cancers. In one member’s practice, carcinoma of unknown primary represents more than 10 percent of NGS orders. Based on these clinical situations, there is concern that these changes will limit patient access to NGS testing needed to appropriately guide treatment.

As a third example, cancers of the digestive tract may be so extensive that it is impossible to determine their primary site, in which case C48.2 or C26.0 would be used appropriately.

Beyond the three examples above, there are many unprecedented cases for which these deleted ICD-10 codes would be correctly coded, and their removal will lead to restricted patient access, even if the original code used remains accurate for diagnosis. **The examples above demonstrate why this transmittal should be rescinded and all the ICD-10 codes targeted for deletion should be retained in the coverage policy.**

Thank you for the opportunity to provide feedback on this important topic. AMP would be happy to have a follow-up conversation with the Coverage and Analysis Group to discuss these concerns and answer any questions that you may have. Please direct your correspondence to Sarah Thibault-Sennett, Senior Manager, Public Policy and Advocacy, at sthibaultsennett@amp.org.

Sincerely,

Antonia R. Sepulveda, MD, PhD
President, Association for Molecular Pathology

¹ Ruqayya Naheed Khan, Muhammad Asad Parvaiz, Amina Iqbal Khan, Asif Loya. Invasive carcinoma in accessory axillary breast tissue: A case report, *International Journal of Surgery Case Reports*; 59 (2019) 152-155.

<https://doi.org/10.1016/j.ijscr.2019.05.037>

² Thasanabanchong, P., Vongsaisuwon, M. Unexpected presentation of accessory breast cancer presenting as a subcutaneous mass at costal ridge: a case report. *J Med Case Reports* **14**, 45 (2020). <https://doi.org/10.1186/s13256-020-02366-0>

³ Ananthula A, Lockwood B, Savage J, Malak S, Chen C, Makhoul I, Pennisi A. Primary Breast Carcinoma of the Vulva Metastatic to Lymph Nodes and Bones: A Case Report and Literature Review. *Perm J*. 2020;24:19.084. doi:10.7812/TPP/19.084.

⁴ Gueye L, Thiam M, Gueye SM, Phiri A, Ndiaye MM, Mahamat S, Diop AP, Cisse ML. Infiltrating tubular-papillary carcinoma of supernumerary left breast: A case report. *J Case Rep Images Obstet Gynecol* 2019;5:100047Z08LG2019.

⁵ Grossi NA. Supernumerary breast tissue: historical perspectives and clinical features. *South Med J*. 2000 Jan;93(1):29-32. PMID: 10653061.

APPENDIX A:

ICD-10 Codes Identified by AMP that Should not be Removed from NCD:

Note: Other ICD-10 Codes not Discussed in this Response May Also Have Clinical Indications that Justify Being Retained.

- ICD-10 Codes Specific to Breast Cancer that Should Not be Removed:
 - C50.019: Malignant neoplasm of nipple and areola, unspecified female breast
 - C50.029: Malignant neoplasm of nipple and areola, unspecified male breast.
 - C50.119: Malignant neoplasm of central portion of unspecified female breast.
 - C50.129: Malignant neoplasm of central portion of unspecified male breast.
 - C50.219: Malignant neoplasm of upper-inner quadrant of unspecified female breast.
 - C50.229: Malignant neoplasm of upper-inner quadrant of unspecified male breast.
 - C50.319: Malignant neoplasm of lower-inner quadrant of unspecified female breast
 - C50.329: Malignant neoplasm of lower-inner quadrant of unspecified male breast.
 - C50.419: Malignant neoplasm of upper-outer quadrant of unspecified female breast
 - C50.429: Malignant neoplasm of upper-outer quadrant of unspecified male breast.
 - C50.519: Malignant neoplasm of lower-outer quadrant of unspecified female breast.
 - C50.529: Malignant neoplasm of lower-outer quadrant of unspecified male breast.
 - C50.619: Malignant neoplasm of axillary tail of unspecified female breast.
 - C50.629: Malignant neoplasm of axillary tail of unspecified male breast
 - C50.819: Malignant neoplasm of overlapping sites of unspecified female breast
 - C50.829: Malignant neoplasm of overlapping sites of unspecified male breast.
 - C50.919: Malignant neoplasm of unspecified site of unspecified female breast
 - C50.929: Malignant neoplasm of unspecified site of unspecified male breast.
 - C80.0: Disseminated malignant neoplasm, unspecified

- ICD-10 Codes Specific to Ovarian Cancer that Should Not be Removed:
 - C57.00: Malignant neoplasm of unspecified fallopian tube
 - C56.9: Malignant neoplasm of unspecified ovary
 - C57.4: Malignant neoplasm of uterine adnexa, unspecified.
 - C80.0: Disseminated malignant neoplasm, unspecified

- ICD-10 Code Specific to Paget Disease that Should Not be Removed:
 - C44.501: Unspecified malignant neoplasm of skin of breast.

- ICD-10 Code Specific to Digestive and Organs Abdominal Structures that Should Not be Removed:
 - C48.2: Malignant neoplasm of peritoneum, unspecified
 - C26.0: Malignant neoplasm of intestinal tract, part unspecified