COLLEGE of AMERICAN PATHOLOGISTS

CAP Cancer Protocols
Summary of Changes
August 2018

The College of American Pathologists August 2018 release contains 21 revised cancer protocols and 4 revised biomarker templates. The majority of the revisions to the cancer protocols are minor updates for formatting, minor corrections, or clarifications to the explanatory notes. The most significant revision is the redesigned central nervous system protocol. The female reproductive protocols are modified to allow for easier reporting when lymph nodes are uninvolved. The prostate protocol includes updates to the biopsy case summaries. The breast biomarker template is revised to reflect the current guidelines and accreditation requirements. The head and neck protocols contain updated 2018 AJCC staging content.

Group	Protocol	New Version	Change(s)
Breast	Breast Biomarker	v1.2.0.1	HER2 Updated interpretation notes
CNS	CNS	v4.0.0.0	Major Revision see House of Delegates notes at the end of this document
Female Reproductive	Endometrium	v4.1.0.0	Margins - Distance of invasive carcinoma from margin (millimeters): ___ mm CHANGED from cm Regional Lymph Nodes - Revised the format to clarify reporting involved and uninvolved nodes
Female Reproductive	Ovary, Fallopian Tubes, Peritoneum	v1.1.0.0	Regional Lymph Nodes - Revised the format to clarify reporting involved and uninvolved nodes
Female Reproductive	Uterine Cervix	v4.1.0.0	Regional Lymph Nodes - Revised the format to clarify reporting involved and uninvolved nodes Vaginal Cuff Margin added to margin section
Female Reproductive	Uterine Sarcoma	v4.1.0.0	Regional Lymph Nodes - Revised the format to clarify reporting involved and uninvolved nodes
Female Reproductive	Vagina	v4.1.0.0	Regional Lymph Nodes - Revised the format to clarify reporting involved and uninvolved nodes
Female Reproductive	Vulva	v4.1.0.0	Regional Lymph Nodes - Revised the format to clarify reporting involved and uninvolved nodes
General	DNA Mismatch Repair Biomarker	v1.0.0.1	Changed MSI response from Indeterminate to Cannot be determined
GI-Hepatobiliary	Distal Extrahepatic Bile Ducts	v4.0.0.1	Margin responses changed from dysplasia to intraepithelial neoplasia
GI-Lower	Appendix	v4.0.0.1	Explanatory Notes added clarification for pT
GI-Lower	Colon Rectum	v4.0.1.0	Tumor Site: Rectosigmoid (removed “region”) pT: added notes added: + Status of Non-Invasive Tumor at Margin(s)
GI-Lower	Colon Rectum Biomarker	v1.2.0.1	Changed MSI response from Indeterminate to Cannot be determined
GI-Soft Tissue	GIST	v4.0.1.0	Regional Lymph Nodes pN: Conditionally required if nodes are present pN0 changed definition to AJCC approved “No regional lymph node metastasis”
Head and Neck	Larynx	v4.0.0.1	Modified pN2b and pN2c for “Metastases” and pN3, pN3b to include “a single contralateral node of any size and ENE(+)”

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Head and Neck	Oral Cavity	v4.0.0.1	Tumor Site and Note A to remove mandible and maxilla pT3 and T4a to reflect May 2018 revised AJCC definitions. pN2b and pN2c for “Metastases” and pN3, pN3b to include “a single contralateral node of any size and ENE(+)”
Head and Neck	Major Salivary Glands	v4.0.0.1	Modified pN2b and pN2c for “Metastases” and pN3, pN3b to include “a single contralateral node of any size and ENE(+)”
Head and Neck	Nasal Cavity	v4.0.0.1	Modified pN2b and pN2c for “Metastases” and pN3, pN3b to include “a single contralateral node of any size and ENE(+)”
Head and Neck	Pharynx	v4.0.0.1	Primary Tumor pT Nasopharynx: pT0 - revised typographical error (duplicate description) Hypopharynx: Corrected descriptions for pT3, pT4a and pT4b Regional Lymph Nodes pN For HPV-Unrelated (Negative) Oropharynx and Hypopharynx: Modified pN2b and pN2c for “Metastases” and pN3, pN3b to include “a single contralateral node of any size and ENE(+)”
Male Genital	Prostate	v4.0.3.0	Significant modifications and additions to the Biopsy Case Summaries
Other	Soft Tissue	v4.0.1.0	Regional Lymph Nodes pN: Conditionally required if nodes are present pN0 changed definition to AJCC approved “No regional lymph node metastasis”
Pediatrics	Neuroblastoma	v3.1.0.3	Minor revision to note for INPC - Ganglioneuroblastoma, intermixed (Schwannian stroma-rich), any age
Skin	Melanoma	v4.0.1.0	Deep Margins: added reporting options for melanoma in situ Revised notes
Thorax	Lung	v4.0.0.3	Modified: Tumor Site responses Margin response - All margins are uninvolved by carcinomatumor Stage format change to allow for “parent” selection
Thorax	Lung Biomarker	V1.3.0.2	Minor revision: added missing note to RET Rearrangement

CNS Cancer Protcol v4.0.0.0 HOD Comments	Response from Author Panel	Revision Required?
Reorganize the biomarkers so that the first group are 2016 WHO tumor designations and the second group are the other biomarkers. Additional biomarkers/tests not used in 2016 WHO tumor designations but often used for diagnostic or prognostic purposes and may be available in many institutions or are frequently requested. Is it possible to organize the biopmarker as: Required for WHO diagnostic designation and if that information is not available one should sign out the case as "Diagnosis - NOS." The next set of markers may be the IHC markers that may be more frequently available and helpful in making the diagnosis and MGMT assay is frequently requested by the treating oncologist - hence may be more likely available at many centers. The remaining biomarkers mostly require molecular studies and would be available at a limited number of academic centers and hence may become an "optional" part of the synoptic Add to the end of the first paragraph in Biomarker Information Note D: Biomarkers formally used for diagnosis, however, are currently few: 1) 1p and 19q codeletion for oligodendrogliomas; 2) IDH1 and IDH2 mutational status for diffuse gliomas (including oligodendrogliomas, infiltrative astrocytomas and glioblastomas); 3) the H3K27M mutant protein for diffuse midline gliomas, and 4) INI1 testing for atypical teratoid/rhabdoid tumors (AT/RT). It is advisable, when making a diagnosis of an astrocytoma or oligodendroglioma, WHO grades II or III, that, at minimum, IDH 1 and 1p/19q testing be performed. H3K27M mutant protein immunohistochemistry should be performed when making a diagnosis of a diffuse midline glioma, and the diagnosis of AT/RT requires demonstrating the loss of INI-1 staining within tumor cells (see accompanying table from the International Collaboration on Cancer Reporting (ICCR)).	As the list of "required" biomarkers will inevitably continue to grow, it is preferable to keep ALL biomarkers in easily searchable alphabetical order. The CAP will consider ways to demonstrate "required" elements with alternate formatting. This text was added to Note D: Currently, the 2016 WHO Classification of Tumours of the Central Nervous System and the 2017 (WHO) Pathology & Genetics of Tumours of Endocrine Organs incorporates molecular genetic studies into several entities while the diagnosis of the majority of CNS tumors remain largely morphologic.1,2 It is expected that, as our understanding of the biology of CNS tumors improves, the list of entities requiring molecular genetic studies will continue to grow. For those defined entities, the use of the biomarker template is encouraged.	**Yes**
I suggest adding "The protocol may not be applicable to biopsy specimen if the tissue sample is limited." CAP Cancer Protocols are designed and intended to standardize cancer reporting for definitive resection of tumors. If sample size limited or only few tumor cells present, pathologist's priority is to render a histopathological diagnosis. After frozen sections, H & E sections and immunohistochemistry, there might not be much left on the tissue block for molecular test or answering most of the questions on the protocol. This will help to prevent problems with hospital accreditation agencies (such as Joint commission or American college of Surgeon Oncology credit program etc.) an hospital's tumor registry and cancer committee. Although the CAP intended the cancer protocols as voluntary tool for pathologists, however, because CAP's name recognition and authority, other aforementioned agencies and hospitals start enforcing its implementation as de facto mandatory. Sometimes it is difficult for non-pathologist to understand why cancer protocol cannot apply to every case.	This point is well taken and is applicable for all protocols, not just the CNS. Tissue adequacy is briefly addressed in Note G and biopsy size in Note H. However, the note section (H) has been expanded to highlight this issue. A comment in the report referring to the limited sample size should suffice.	**Yes**
As I discussed during the teleconference, in the electronic version, if we can build pull-down features in to the template, it will make the template easier to read and more concise. I also agree that having drop-down boxes would be extremely valuable - but is likely to be a goal for the future.	This may be possible in the future based on software limitations for the eCC dataset and vendor software requirements.	**No**

CNS Cancer Protcol v4.0.0.0 HOD Comments	Response from Author Panel	Revision Required?
In our department (and many pathologists in other groups too as far as I know), we standardize our pathology report diagnostic heading as follows: *Tissue type, Anatomic location (including laterality if applicable), Procedure type - Histopathology Diagnosis, (if malignant) Differentiation/ tumor grade.* If a pathology report contains these information in the heading, it would be unnecessary and tedious to repeat the same information in the synaptic report template. By reformat, we may be able to make the template more concise. This suggestion may also applicable to other cancer protocols. While I agree with the comments regarding duplication of information in the diagnosis and the synoptic, the latter provides discrete data fields that are easily searchable and hence I would argue that the synoptic headings should stay.	As one of the comments stated, the intent behind the template is to summarize and not necessarily replace.	**No**
I suggest delete “Neuroimaging Findings” from the protocol. It is important for pathologists to correlate with radiographic information in order to reach correct pathological diagnosis. (personally, I read radiology reports, reviewing CT and MRI images on my computer or talk to radiologists almost daily.) However, radiology findings, if relevant, shall be part of patients’ clinical history, belongs to that section rather than being in the pathology synoptic report. I would not rely on other pathologist to tell me what the radiographic finding was, neither clinicians or patients depending on pathology reports as source of the radiographic information. Besides, radiographic reports can sometimes be inconclusive or even wrong. Agree with deleting neuroimaging findings. As a general pathologist, I understand the importance of neuro imaging, but rely on discussion with radiologists and neurosurgeons rather than interpreting the imaging myself. I am truly split on the issue of including or deleting neuroimaging findings. While knowing that the lesion is a ring-enhancing lesion, or that there are multiple lesions can be very helpful in making the diagnosis I would want to see it in there. On the other hand it is difficult and impractical (particularly in smaller practice groups) to find and add the relevant findings from elsewhere in the medical record. It would be time-consuming and as stated it would be someone else’s interpretation, may be inconclusive and sometimes incorrect. Again remembering that components of the synoptic are optional one could always add N/A and move on. But if the information is available - it would be desirable to retain the neuroimaging line.	Neuroimaging Findings will remain. Please remember that all elements in the protocol are optional.	**No**
The statement at the top of the case summary should be modified as the Synoptic is occasionally ‘required’ by certain agencies and in some cases even CAP inspectors have cited institutions for not using the CNS synoptic. We should therefore emphasize this in some manner. (I am not sure that we could make a generic statement that it may not apply to samples with limited tissue - that's a slippery slope). Note: This case summary is recommended for reporting the integrated diagnosis for CNS neoplasms, but is not required for accreditation purposes.	The CAP repeatedly states that the use of the CNS template is recommended but not required.	**No**
A general comment not in particular to the CNS protocol. The CAP’s intention and efforts shall be applauded. However, when we develop and implement tumor templates or other regulatory requirements, not only they shall create value to clinicians and help patients, also facilitate pathologists rendering accurate diagnosis and improving efficiency. Pathologists, like any other specialties, do not have unlimited time. When the mandate becomes tedious and burdensome, the compliance will decrease and frustration increases. We hope CAP leadership and panel members keep that in mind, improving efficiency and simplifying protocol shall be part of the agenda. After all, Pathologists are our main constituents. We shall at least trying to make their life easier if possible so to speak.	The authors of the CNS Cancer Protocol are very mindful of the risk of increasing the administrative burden for its constituents and have eliminated as many items as possible while trying to strike a balance. Fortunately, the use of this template is now optional.	**No**

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January 2018

The College of American Pathologists January 2018 release contains 27 revised cancer protocols, 2 revised biomarker templates, and 1 new biomarker template. The majority of the revisions to the cancer protocols are minor updates for formatting or corrections or clarifications to the explanatory notes. The most significant revisions are in the regional lymph node sections of the Breast Invasive and Breast DCIS protocols, which will allow for easier reporting when lymph nodes are uninvolved. The breast biomarker template was also revised to reflect the current guidelines and accreditation requirements. The revised Bone Marrow protocol reflects the current WHO histologic types. The new DNA Mismatch Repair biomarker template is designed for reporting on any specimen being tested for possible Checkpoint Inhibitor Immunotherapy.

	Group	Protocol	New Version	Change(s)
1	Breast	Breast Invasive v4.0.0.0	v4.1.0.0	Modified: Tumor Site: revise format O'clock DCIS response terms Regional Lymph Nodes
2	Breast	Breast DCIS v4.0.0.0	v4.1.0.0	Modified: Tumor Site: revise format O'clock Regional Lymph Nodes
3	Breast	Breast Biomarker v1.1.0.0	v1.2.0.0	Added + Testing performed on block + Cold Ischemia Time: _____ minutes + Fixation Time: ____ hours Modified ER and PgR - Average intensity of staining (changed from optional to required to match ASCO/CAP and LAP Program requirements) HER2 - Percentage of cells with uniform intense complete membrane staining (report only for 2+, 3+)
4	Endocrine	Adrenal Gland v4.0.1.0	V4.0.1.1	Modified: Tumor Extension
5	Endocrine	Appendix NET v4.0.0.0	v4.0.0.1	Corrected Notes for area on table to $2mm^2$
6	Endocrine	Colon NET v4.0.0.0	v4.0.0.1	Corrected Notes for area on table to $2mm^2$
7	Endocrine	Duodenum ampulla NET v1.0.0.0	v1.0.0.1	Corrected Notes for area on table to $2mm^2$
8	Endocrine	Jejunum Ileum NET v1.0.0.0	v1.0.0.1	Corrected Notes for area on table to $2mm^2$
9	Endocrine	Pancreas-endocrine v4.0.0.0	v4.0.0.1	Corrected Notes for area on table to $2mm^2$
10	Endocrine	Stomach NET v4.0.0.0	v4.0.0.1	Corrected Notes for area on table to $2mm^2$

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	Group	Protocol	New Version	Change(s)
11	Gastrointestinal	Pancreas-exocrine v4.0.0.0	v4.0.0.1	Added Procedure - enucleation Added Margins - enucleation specimens
12	Gastrointestinal	Perihilar Bile Ducts v4.0.0.0	v4.0.0.1	Modified: Tumor Extension
13	Genitourinary	Kidney v4.0.1.0	v4.0.1.1	Modified: Histologic Type
14	Genitourinary	Prostate v4.0.1.0	v4.0.2.0	Modified: Tumor quantitation – Change from core/required to optional element
15	Genitourinary	Urethra v4.0.1.0	v4.0.1.1	Modified: Tumor Extension
16	Gynecologic	Ovary Fallopian Tube v1.0.0.0	v1.0.0.1	Updated Histologic Grade - Notes
17	Hematologic	Bone Marrow v3.0.1.2	v3.1.0.0	Modified: WHO Histologic Types
18	Hematologic	Plasma Cell v1.0.0.1	v1.0.0.2	Modified: Extent of Plasma Cell Infiltrate
19	Pediatric	Ewing v3.2.0.1	v3.2.0.2	Regional lymph node order modified to report number involved before number examined Modified biopsy Extent of Tumor terminology
20	Pediatric	Germcell v3.1.0.1	v3.1.0.2	Regional lymph node order modified to report number involved before number examined
21	Pediatric	Hepatoblastoma v3.2.0.1	v3.2.0.2	Regional lymph node order modified to report number involved before number examined
22	Pediatric	Neuroblastoma v3.1.0.1	v3.1.0.2	Regional lymph node order modified to report number involved before number examined
23	Pediatric	Rhabdomyosarcoma v3.2.0.1	v3.2.0.2	Regional lymph node order modified to report number involved before number examined
24	Pediatric	Wilms v3.2.0.1	v3.2.0.2	Regional lymph node order modified to report number involved before number examined
25	Skin	Skin Melanoma v4.0.0.0	V4.0.0.1	Modified: Notes
26	Skin	Melanoma Biomarker v1.0.0.1	v1.0.0.2	Corrected HGVS nomenclature - KIT Mutational Analysis
27	Skin	Merkel Cell Carcinoma v4.0.0.0	v4.0.0.1	Modified : Tumor Extension
28	Thorax	Lung v4.0.0.1	v4.0.0.2	Modified: Histologic Type
29	Thorax	Plural Mesothelioma v4.0.0.0	v4.0.0.1	Modified : Tumor Extension
30	Thorax	Thymus v4.0.0.0	v4.0.0.1	Modified :Tumor Extension
		New Biomarker Template	**Version**	
1	General	DNA Mismatch Repair v1.0.0.0	v1.0.0.0	New Template developed for Checkpoint Inhibitor Immunotherapy