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Re: Draft Local Coverage Determination - Biomarkers for Oncology (DL35396)

Dear Dr. Patterson:
Thank you for the opportunity to comment on DL35396. The Association for Molecular Pathology (AMP) is an international medical professional association representing approximately 2,300 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 and commercial clinical laboratories, community hospitals, and the in vitro diagnostics industry.

The College of American Pathologists (CAP) is a national medical specialty society representing more than 18,000 physicians who practice anatomic and/or clinical pathology. College members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

Members of both AMP and CAP are experts in molecular pathology and the implementation of this coverage policy will directly impact their practices. We are submitting joint comments because at this time both of our organizations share the same concerns regarding this draft LCD, and, as such, we request that Novitas consider the joint recommendations outlined in this letter.

We would like to express our gratitude for your proposal to cover many of these molecular diagnostic services. Additionally, many of the cancers listed in your draft LCD can also be tested using the FISH methodology. We write this letter under the assumption that FISH testing will be covered, and because it is outside the scope of this dLCD. With regard to non-FISH molecular diagnostic services, we do believe that the medical literature supports some modifications and additions to Novitas' proposed policy. Our specific recommendations are described below.

Coverage Determinations

Colorectal Carcinoma

We agree with your decision to cover KRAS 12/13, KRAS 61, KRAS 146, NRAS, BRAF, and MSI for patients with Colorectal Carcinoma. Regarding your decision to cover PIK3CA (CPT code 81404) mutation testing, we would caution you that evidence for coverage of this analyte may not yet be mature at the present time.
While we agree with your decision to cover the various MLH1 analytes, we are not certain that the CPT codes included in the draft LCD are appropriate. The draft provides coverage for CPT codes 81292, 81293, and 81294, which are all for germline testing of MLH1, but CPT code 81288 is specifically intended for MLH1

promoter hypermethylation testing, which is referenced in the LCD. Please clarify if the dLCD was intended to include the CPT code 81288. If not, we believe that CPT code 81288 is appropriately utilized for this testing, and should be covered.

Non-Small Cell Lung Cancer (NSCLC)

We agree with your decision to cover KRAS and BRAF for patients with NSCLC. However, evidence may be immature at the present time for the use of KRAS 61 and KRAS 146 (CPT code: 81276). Abundant evidence additionally supports ALK testing for NSCLC patients. While many laboratories test for ALK using FISH methodology, some do test using non-FISH molecular methods. Therefore, we recommend that the CPT code 81401 be covered to reimburse labs for ALK non-FISH fusion gene testing (see specifically noted Tier 2 analyte 41401 EML/ALK (inv(2))(eg, non-small cell ung cancer), translocation or inversion analysis).

We also appreciate your inclusion of ICD-10 codes used to "rule out" certain conditions that may initially mimic NSCLC; this allows providers to robustly and effectively diagnose their patients.

Melanoma

We support Novitas' proposal to cover BRAF, KIT and NRAS testing for patients with melanoma.

Brain

We agree with the proposal to cover BRAF, MGMT promoter hypermethylation, IDH1, IDH2 and PIK3CA molecular testing for patients with brain cancer. Regarding coverage for CPT code 81235 for EGFR, we request clarification whether this code will be used for variant testing (for example the common EGFRvIII deletion variant in glioblastomas) or for EGFR amplifications. We are not sure that CPT code 81235 ("common variants" of EGFR) covers the relevant approach to utilization of the EGFR biomarker in brain tumors. Regarding your decision to cover PTEN testing, we ask for clarification on whether this is intended to serve PTEN amplifications, most commonly tested by FISH, but which can also be tested using non-FISH molecular methodologies.

We would also like to caution that the evidence base for CIMP testing in brain tumors may not be mature at the present time.

Thyroid

We agree with your proposal to cover BRAF, KRAS, HRAF, PIK3CA, RET, PAX8/PPAR and ThyraMIR for this patient population. In order to comply with the most current evolving practice, we also request that you consider coverage for TERT Promoter Mutation (Liu and Xing, 2014; De Tao and Kun, 2016.) Practice patterns also support coverage for RET/PTC fusions in this population. (Arbor and Orazi, 2016; Nikiforov and Ohori, 2011).

Gynecological

Regarding coverage of molecular testing for patients with gynecological cancers, we request that you add coverage for somatic mutational analysis BRCA 1/2, using CPT code 81211. There is a strong evidence base for the use of BRCA1/2 mutational testing in conjunction with use of PARP inhibitors, specifically Olaparib. Specifically, the FDA-approved drug label for Olaparib requires BRCA1/2 mutational analysis, as it is a predictor of response to therapy. We support your proposal to cover TP53, MSI testing and MLH1 testing. We would like to request clarification to ensure that Novitas intends to cover CPT codes 81292, 81293, and 81294 for MLH1 for gynecologic cancers; we believe that CPT code 81288 (MLH1 promoter methylation) should also be covered (This item is also addressed above in the section on colorectal carcinoma).

We also agree with your decision to cover PTEN. However, we believe that the evidence may not be mature at the present time to support coverage for PIK3CA (81404), RAD51C, RAD51D, KRAS (81275), BRAF (81210), and AKT1 for gynecological cancers.

Please also consider coverage for STK11(LKB1) gene testing (81404, 81405) , which has been recommended for individuals meeting clinical criteria for Peutz-Jeghers syndrome. Patients with this syndrome are at increased risk for ovarian cancer.

Urinary

We agree with the proposal to cover molecular testing for MSI and MLH1 in patients with urinary tract cancer, and thank you for the careful consideration with which the ICD-10 codes were chosen to highlight anatomic sites of urinary tract tumors most associated with MSI and MLH1 promoter hypermethylation testing. Also, we appreciate Novitas' recognition that MLH1 variants are found in a subset of urinary tumors. However, we request clarification regarding the covered CPT codes and believe that CPT code 81288 (MLH1 promoter methylation) should be added.

GIST

AMP and CAP support Novitas' decision to cover for KIT and PDGFRA in patients with GIST. NCCN guidelines call for SDH gene testing in GIST that is negative for KIT and PDGFRA mutation (NCCN Clinical Guidelines: Gastric Cancer).

ALL

We support Novitas' decision to cover BCR/ABL1, ABL1 (kinase domain), IGH, TCRB, TCRG, MLL/AF4, E2A/PBX1, and ETV6/RUNX1 for patients with ALL.

AML

We support Novitas' decision to cover PML/RARA, RUNX1/RUNX1T1, CBFB/MYH11, FLT3 ITD, NPM1, CEBPA, IDH1, IDH2, and DNMT3A for patients with AML. However, this is another instance where the evidence might not yet be mature to support coverage for KRAS, NRAS, and FLT3 D836.

Please also consider covering ASXL1, KIT (81272), TP53 (81404, 81405), RUNX1, GATA1, WT1, TET2 to comply with the WHO guidelines for diagnosis and prognosis of certain acute myeloid leukemias (to be released in 2016). Additionally, certain genes now known to be implicated in myeloid neoplasms with germline predisposition (DDX41, ANKRD26, GATA2), will require testing in the specific clinical setting (Arber et al, Blood 2016; PMID: 27069254)

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Hairy Cell Leukemia

Regarding your coverage proposals for Hairy Cell Leukemia, we support coverage for IGH. We also recommend coverage for MAP2K1 (CPT code 81406) and BRAF V600E (CPT code 81210) mutations for diagnosis as outlined in the World Health Organization (WHO) guidelines. (Foucar and Falini, 2008).

Aplastic Anemia

We agree with Novitas' proposal to cover TCRB and TCRG as part of workup and minimal residual disease monitoring.

Burkitt Lymphoma

We agree with Novitas' proposal to cover IGH as part of Burkitt lymphoma workup, however evidence for the use of TP53 in patients with Burkitt Lymphoma may not yet be mature. We also recommend that Novitas cover testing for EBV (Epstein-Barr virus) (CPT code: 87799) as its utility has been proven in this population. (Gulley and Tang, 2008).

Myeloproliferative Diseases

We support coverage of BCR/ABL1, JAK2 (p.V617F), JAK2 (exon 12), MPL, CALR, and CSF3R for diagnosis and, ASXL1, TET2, EZH2, ETNK1, SETBP1, and CALR (exon 9) for prognosis in these instances. Please

also consider adding SRSF2, IDH1, IDH2, and SF3B1 to comply with the WHO's criteria for diagnosis of Primary Myelofibrosis in the absence of JAK2, MPL, CALR mutations. (Arber and Atila, 2016). NCCN guidelines also support the testing of these genes, and notes that "in ambiguous cases of BCR-ABL1 negative Myeloproliferative Neoplasms, further mutational analysis may help document clonality and define the entity. For example, mutations involving multiple genes such as JAK2, MPL, CALR, TET2, ASXL1, CBL, EZH2, IDH, DNMT3A, LNK, RAS and IKZF1 have been described in BCR-ABL-negative MPNs (NCCN Clinical Practice Guidelines: Chronic Myelogenous Leukemia).

We also request you consider coverage for CBL and RUNX1 supported by the above referenced NCCN guidelines.

T-cell Prolymphocytic Leukemia
We support Novitas' proposal to cover TCRG and TCRB gene rearrangement studies. Based on 2008 WHO recommendations and NCCN Guidelines, we also request that you consider including coverage for STAT3 (81405), STAT5B, and ATM (81408) for diagnostic purposes (NCCN Clinical Practice Guidelines: Non-Hodgkin's Lymphoma; Campo and Swerdlow, 2008).

Chronic Myeloid Leukemia and Chronic Myelomonocytic Leukemia
We support Novitas' proposal to cover ABL1 KD and BCR ABL1 for patients with CML and CMML as supported by NCCN guidelines. We also appreciate that FLT3 ITD is covered, as it, along with KIT and JAK2, for which coverage is also proposed, are utilized as drug targets in this patient population. We recommend that ASXL1 testing also be covered, as these mutations are an independent adverse prognostic indicator.

Chronic Lymphocytic Leukemia
We support Novitas' coverage of IGH, IGH somatic hypermutation, ATM and TP53 for this patient population. However, IGH direct probe method (CPT code 81262) is not a common method to test for IGH clonal rearrangements at this time. In addition to the markers listed in the proposed policy, please consider adding coverage for prognostic biomarkers (recent evidence and NCCN guidelines) SF3B1 and NOTCH1 (Ref: NCCN Oncology Guidelines: Non-Hodgkin's Lymphoma; Baliakas and Hadzidimitriou, 2014; Nadeu and Delgado, 2016; Rossi and Rasi, 2012; Villamor and Conde, 2012).

Follicular Lymphoma
We support Novitas' proposal for coverage of diagnostic (DX) molecular testing in follicular lymphoma, however, we believe that the name-specific test should precede the term "DX" in follicular lymphoma section of the LCD. The appropriate test should be t(14;18)/IGH-BCL2 (CPT code: 81402) as outlined in NCCN guidelines. We request that you change the inaccurate term DX to cover IGH-BCL2 translocations (NCCN Clinical Practice Guidelines: Non-Hodgkin's Lymphoma).

Mantle Cell Lymphoma
We agree with Novitas' coverage of CCND1/IGH in this patient population.

Mastocytosis
We agree with Novitas' coverage of KIT in this patient population.

Myelodysplastic Syndrome
We support Novitas' coverage of FLT3 ITD, FLT3 D836, NPM1, KRAS, NRAS, KIT, CEBPA, IDH1, IDH2, DNMT3A, JAK2 (p. V617), ASXL1, EZH2, and TET2 in this patient population. However, we believe that the evidence might be currently immature for coverage of JAK2 (exon 12) and MPL. In our section on ICD-10 codes, below, we have highlighted specific "rule out" diagnosis codes that we believe should be added to the

LCD, as they often mimic clonal MDS (versus a benign etiology) in a patient being evaluated for cytopenia. Additionally, we request that you consider adding coverage for the following analytes: RUNX1 (81401), GATA2, TP53, ETV6 (81401), SF3B1, SRSF2, U2AF1, ZRSR2, CBL, SETBP1, all of which have been recommended for use by the NCCN (NCCN Clinical Guidelines: Myelodyspastic Syndrome).

Myeloma Gene Expression Profile
We support Novitas' coverage of myeloma gene expression. Please consider adding synonymous terms "plasma cell myeloma" and "multiple myeloma" for "myeloma" during the coverage review (NCCN Clinical Practice Guidelines: Multiple Myeloma).

Hereditary Neuroendocrine Tumors
Please consider coverage for MAX, SDHB, SDHC, SDHD, TMEM127, and VHL (CPT code 81437) and SDHB, SDHC, SDHD, VHL (CPT code 81438) for this patient population.

Cytogenomic Array
We support the coverage of cytogenetics array in myeloid neoplasms and acute lymphoblastic leukemia/lymphomas, especially if the conventional cytogenetic studies fail and the limited fluorescence in-situ hybridization studies currently utilized are negative. Cytogenetic abnormalities (both number and type) are a big part of categorizing the myelodysplastic syndromes based on prognosis. In ALL, it helps in differentiating hypodiploid clone from a pseudo-hyperdiploid clone which would not be picked up by other methodologies and also identifying other chromosomal abnormalities.

Hypereosinophilia Syndrome
We support Novitas' coverage proposal for KIT (including p.D816V) and FIP1L1/PDGFRA Fusion in this population.

Additional Diagnoses Recommended by AMP and CAP Conditions for Coverage

Extranodal Marginal Zone Lymphoma/Gastric MALT Lymphoma
Based on 2008 WHO classifications, please consider adding coverage for IGH gene rearrangements (CPT code 81261) for the diagnostic workup of this patient population.

Anaplastic Large Cell Lymphoma
Based on 2008 WHO classifications, please consider adding coverage for TCR gene rearrangement (TCRG, CPT code 81432; TCRB, CPT code 81430) for this patient population (Campo and Swerdlow, 2008).

Splenic or Nodal Marginal Zone Lymphoma
Based on 2008 WHO classifications, please consider adding coverage for IGH gene rearrangements (CPT code: 81261) for the diagnostic workup of this patient population.

Waldenstrom Macroglobulinemia/Lymphoplasmacytic Lymphoma
Based on NCCN guidelines, please consider adding MYD88 mutation analysis for this patient population. NCCN guideline lists MYD88 as "essential" for the workup of this patient population.

MF/Sezary Syndrome
Based on the 2008 WHO classification, we request that you consider coverage for TCR gene arrangement (TCRG, CPT code 81432; TCRB, CPT code:81430) in this population (Campo and Swerdlow, 2008).

Post-Transplant Lymphoproliferative Disease
Please consider adding coverage for EBV (CPT code 87799) for patients in this population (Gulley and Tang, 2008).

Follicular Dendritic Cell Sarcoma
For patients in this population, please consider adding coverage for BRAF (CPT code: 81210), in compliance with 2016 WHO guidelines (Campo and Swerdlow, 2016).

Erdheim Chester Disease
For patients in this population, please consider adding coverage for BRAF (CPT code 81210), in compliance with 2016 WHO guidelines (Campo and Swerdlow, 2016).

Langerhans Cell Histiocytosis
Based on the 2016 WHO revisions, please consider adding coverage for BRAF (CPT code 81210) and MAP2K1 (CPT code 81406) for this patient population (Campo and Swerdlow, 2016).

Aggressive NK-Cell Leukemia
Based on 2008 WHO updates, we recommend you consider coverage for the use of TCR gene rearrangement (TCRG, CPT code: 81432; TCRB, CPT code: 81430) for diagnostic purposes in this patient population (Campo and Swerdlow, 2008).

Sarcoma
We note that GIST is the only sarcomatous lesion addressed in the draft policy. NCCN Guidelines support the addition of coverage for CPT code 81401 (tier 2, level 2 translocation fusion gene detection) for sarcoma patients. Establishing a defined fusion gene event is instrumental in the diagnosis of these patients and, in some cases, also has therapeutic implications (NCCN Guidelines for Soft Tissue Sarcoma). Also, as the histologic appearance of many different sarcomas is often indistinguishable, a common lab practice is to test these tumors simultaneously for many different sarcoma-associated gene fusions, thus necessitating the use of multiple units of 81401. Please see our recommendations of additional ICD-10 codes below that should be covered to appropriately test for sarcomas. We specifically note that since sarcomas do not tend to be restricted as to anatomical location, the list of potentially applicable ICD-10 codes for which a sarcoma diagnosis or a sarcoma rule-out diagnostic workup may apply is quite large.

Extranodal NK/T-cell Lymphoma, Nasal Type
We request that Novitas consider adding coverage for TCR gene rearrangement (TCRG, CPT code: 81432; TCRB, CPT code: 81430) and EBV (CPT code: 87799) for this patient population, based on 2008 WHO classifications (Campo and Swerdlow, 2008).

Enteropathy-Associated T-cell Lymphoma
Please consider adding coverage for TCR gene rearrangement (TCRG, CPT code: 81432; TCRB, CPT code: 81430) for this patient population, based on 2008 WHO classifications (Campo and Swerdlow, 2008).

Hepatosplenic T-cell Lymphoma
Please consider adding coverage for TCR gene rearrangement (TCRG, CPT code: 81432; TCRB, CPT code: 81430 for this patient population, based on 2008 WHO classifications (Campo and Swerdlow, 2008).

Subcutaneous Panniculitis-like T-cell Lymphoma
Please consider adding coverage for TCR gene rearrangement (TCRG, CPT code: 81432; TCRB, CPT code: 81430) for this patient population, based on 2008 WHO classifications (Campo and Swerdlow, 2008).

Chimerism Analysis for Stem Cell Transplantation Coding
In addition to the requests above, please consider coverage for chimerism analysis (CPT codes 81267 and 81268) for all hematopoietic neoplasms after stem cell transplantation to conform to the standard of care at all transplant centers.

Diffuse Large B cell lymphoma, T cell large granular lymphocytic leukemia, lymphoproliferative disorder of childhood

We request that Novitas consider adding coverage for EBV (CPT code: 87799) for these patient populations (NCCN Clinical Practice Guidelines: Non-Hodgkin's lymphoma).

Carcinoma of unknown primary in lymph node of neck, or nasopharyngeal carcinoma

Based on NCCN Guidelines, please consider adding coverage for EBV DNA testing (CPT code: 87799) for this patient population (NCCN Clinical Practice Guidelines: Head and Neck Cancers).

Next Generation Sequencing

We appreciate that Novitas recognizes that much of the "single gene" testing covered in this policy could also be performed by next generation sequencing (NGS), particularly NGS-based testing that examines 5-50 genes (CPT codes 81445 and 81450). However, we believe that Novitas should reconsider requiring that all molecular diagnostic oncology services need to be coded and billed using the "one-at-a-time" biomarker approach. NGS testing is no longer experimental. Significant consensus evidence supports the use of NGS testing in patients with many different types of cancer, and we request that coverage be added for CPT codes 81445 and 81450. Coverage policies released by other payers have recognized that as long as there are at least five gene targets with established clinical utility, code 81445 applies. This "minimal 5-gene" does not endorse the utility of the entire panel. Although we do not believe the current NLA for NGS is appropriately priced, even with appropriate pricing for 81445 or 81450, substantial cost savings could be realized by CMS compared to payment for multiple individual Tier 1 analytes. Other significant patient care advantages of an up-front multi-gene NGS testing algorithm versus a sequential reflexive single-gene testing approach are, 1) a shortened time to accurate diagnosis (and treatment) when all testing is done simultaneously; and 2) the exhaustion of small quantities of DNA (from small biopsies) with sequential single-gene testing (versus up-front multi-gene NGS) such that an accurate diagnosis is not just delayed, but often never determined without a repeat invasive biopsy.

ICD-10 Coding

Based on the evidence provided above, we request that you consider adding the following ICD-10 codes:

C88.8 Other malignant immunoproliferative diseases
C92.2 Atypical chronic myeloid leukemia, BCR/ABL-negative
C92.20 Atypical chronic myeloid leukemia, BCR/ABL-negative, not having achieved remission
C92.21 Atypical chronic myeloid leukemia, BCR/ABL-negative, in remission
C92.22 Atypical chronic myeloid leukemia, BCR/ABL-negative, in relapse
C93 Monocytic leukemia
C93.1 Chronic myelomonocytic leukemia
C93.10 Chronic myelomonocytic leukemia not having achieved remission
C93.11 Chronic myelomonocytic leukemia, in remission
C93.12 Chronic myelomonocytic leukemia, in relapse
C93.3 Juvenile myelomonocytic leukemia
C93.30 Juvenile myelomonocytic leukemia, not having achieved remission
C93.31 Juvenile myelomonocytic leukemia, in remission
C93.32 Juvenile myelomonocytic leukemia, in relapse
C93.Z Other monocytic leukemia
C93.Z0 Other monocytic leukemia, not having achieved remission
C93.Z1 Other monocytic leukemia, in remission
C93.Z2 Other monocytic leukemia, in relapse
C94.40 Acute panmyelosis with myelofibrosis not having achieved remission
C94.41 Acute panmyelosis with myelofibrosis, in remission
C94.42 Acute panmyelosis with myelofibrosis, in relapse
C94.6 Myelodysplastic disease, not classified

D45 Polycythemia vera
D46.A Refractory cytopenia with multilineage dysplasia
D46.B Refractory cytopenia with multilineage dysplasia and ring sideroblasts
D47 Other neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.1 Chronic myeloproliferative disease (CNL, MPD unspecified)
D47.3 Essential (hemorrhagic) thrombocythemia
D47.4 Osteomyelofibrosis
D47.Z Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.Z1 Post-transplant lymphoproliferative disorder (PTLD)
D47.Z9 Other specified neoplasms of uncertain behavior of lymphoid, hematopoietic and related tissue
D47.9 Neoplasm of uncertain behavior of lymphoid, hematopoietic and related tissue, unspecified
D61.81 Pancytopenia
D61.810 Antineoplastic chemotherapy induced pancytopenia
D61.811 Other drug-induced pancytopenia
D61.818 Other pancytopenia
D69.4 Other primary thrombocytopenia
D69.42 Congenital and hereditary thrombocytopenia purpura
D69.49 Other primary thrombocytopenia
D69.5 Secondary thrombocytopenia
D69.59 Other secondary thrombocytopenia
D69.6 Thrombocytopenia, unspecified
D72.810 Lymphocytopenia
D72.821 Monocytosis (symptomatic)
D72.829 Elevated white blood cell count, unspecified
D75.1 Secondary polycythemia
D75.81 Myelofibrosis
D75.82 Heparin induced thrombocytopenia (HIT)
D75.89 Other specified diseases of blood and blood-forming organs
D75.9 Disease of blood and blood-forming organs, unspecified

We respectfully ask that you consider these comments which were prepared by a consortium of providers in the Novitas jurisdiction as well as other members of the Association for Molecular Pathology, laboratory directors, staff and consultants who provide service to Medicare beneficiaries covered by Novitas. We are happy to be of assistance in providing additional clinical information, references, contacts, or whatever is needed to assist you with this draft LCD. Please direct your correspondence to Tara Burke, AMP Policy Analyst, at tburke@amp.org or Nonda Wilson, CAP's Manager, Economic and Regulatory Affairs, at nwilson@amp.org.

References

Ajani, J., D'Amico, T., et. Al (March 2016) NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer, version 1. 2016.

Anderson, K., Alsina M., et. Al (January 2016) NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma, version 3. 2016.

Arber, D., Attilio, Orazi, et. Al, (May 2016) The 2016 revision to the World Health Organization classification of myeloid neoplasms and acute leukemia; Blood, 127 (20) 2391-2405; DOI: 10.1182/blood-2016-03-643544.

Baliakas, P., & Hadzidimitriou, A. (2014). Recurrent mutations refine prognosis in chronic lymphocytic leukemia. Leukemia, 29(2), 329-336. doi:10.1038/leu.2014.196

De-Tao, Y., Kun, Y., Run-Qing, L., Xianghua, L., Jianhui, X., & Mengyuan, L. (2016). Clinicopathological significance of TERT promoter mutation in papillary thyroid carcinomas: A systematic review and meta-analysis. Clin Endocrinol Clinical Endocrinology. doi:10.1111/cen.13017

Foucar K, Falini B, Catovsky D, Stein H. (2008) Hairy Cell Leukaemia. In: Swerdlow SH, Campo E, Harris NL et al, eds. WHO Classification of Tumours of Haematopoietic and Lymphoid Tissues. Lyon: IARC Press.

Gulley, M. L., Tang, W., et. al (2008). Laboratory Assays for Epstein-Barr Virus-Related Disease. The Journal of Molecular Diagnostics, 10(4), 279-292. doi:10.2353/jmoldx.2008.080023

Greenberg, P., & Stone, R. (2015, May 28). NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndrome V. 1, 2016.

Liu, R., and M. Xing. "Diagnostic and Prognostic TERT Promoter Mutations in Thyroid Fine-needle Aspiration Biopsy." Endocrine Related Cancer 21.5 (2014): 825-30. Web.

Nadeu, F., & Delgado, J. (2016). Clinical impact of clonal and subclonal TP53, SF3B1, BIRC3, NOTCH1, and ATM mutations in chronic lymphocytic leukemia. Blood, 127(17), 2122-2130. doi:10.1182/blood-2015-07-659144

Nikiforov, Y. E., Ohori, N. P., et. Al (2011). Impact of Mutational Testing on the Diagnosis and Management of Patients with Cytologically Indeterminate Thyroid Nodules: A Prospective Analysis of 1056 FNA Samples. The Journal of Clinical Endocrinology & Metabolism, 96(11), 3390-3397. doi:10.1210/jc.2011-1469

Rossi, D., & Rasi, S. (2012). Integrated mutational and cytogenetic analysis identifies new prognostic subgroups in chronic lymphocytic leukemia. Blood, 121(8), 1403-1412. doi:10.1182/blood-2012-09-458265

Secord, A., Barnett, J. C., et. al. (2013). Cost-Effectiveness of BRCA1 and BRCA2 Mutation Testing to Target PARP Inhibitor Use in Platinum-Sensitive Recurrent Ovarian Cancer. International Journal of Gynecological Cancer, 23(5), 846-852. doi:10.1097/igc.0b013e31829527bd

Swerdlow, S. H., & Campo, E, et al. (2008). WHO Classification of Tumours, Volume 2. WHO Press.

Swerdlow, S. H., Campo, E., et. al. (2016). The 2016 revision of the World Health Organization (WHO) classification of lymphoid neoplasms. Blood, blood-2016-01-643569. http://dx.doi.org/10.1182/blood-2016-01-643569.

Radich, J., Deninger, M. et. Al. (2015, September 09). NCCN Clinical Practice Guidelines in Oncology: Chronic Myelogenous Leukemia.

Villamor, N., & Conde, L. (2012). NOTCH1 mutations identify a genetic subgroup of chronic lymphocytic leukemia patients with high risk of transformation and poor outcome. Leukemia, 27(5), 1100-1106. doi:10.1038/leu.2012.357

Von Meheren, Margaret, and R. Lor Randall. (2016, Feb) NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma V.2 2016. NCCN.org.

Zelenetz, A., & Gordon, L. (2016, May 3). NCCN Clinical Practice Guidelines in Oncology: Non Hodgkins Lymphoma v. 3 2016.