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August 31, 2015

The Honorable Andy Slavitt
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: 2016 Hospital Outpatient Prospective Payment, Proposed Rule, CMS-1633-P, Exclusion from Conditional Packaging Policy For Molecular Pathology Tests

Dear Administrator Slavitt:

On behalf of the Coalition for 21st Century Medicine (the Coalition), we appreciate the opportunity to comment on the CY 2016 Hospital Outpatient Prospective Payment (OPPS) Proposed Rule. We are writing to comment on the Centers for Medicare & Medicaid Services (CMS) proposal to continue its policy of "conditionally packaging" certain clinical laboratory diagnostic tests listed on the Clinical Laboratory Fee Schedule (CLFS).

In the Proposed Rule, CMS has proposed exempting from the conditional packaging rule CPT codes for all molecular pathology tests, on the basis that these tests have a "different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests. . . ." CMS proposes assigning status indicator "A" to those test codes in Addendum B, indicating that they are to be paid separately on the CLFS. In addition, based on a review of Addendum B, certain Multianalyte Assays with Algorithmic Analyses (MAAA tests) that are based upon DNA or RNA underlying analytes were similarly excluded and also assigned a status indicator of "A." We believe that this rationale is well-founded, and support the agency proposal to continue its policy of excluding "all molecular pathology" test codes from the conditional packaging rule.

We are concerned, however, that CMS did not apply this exemption consistently to all MAAA test codes. Instead, CMS has proposed designating MAAA test codes based on protein underlying analytes as non-payable in the hospital outpatient department. We believe that the policy rationale CMS has offered for exempting molecular pathology test codes from packaging applies equally to all of the new MAAA test codes and not just certain DNA/RNA based MAAA codes. As explained in detail below, these new MAAA codes for protein-based tests meet precisely the same criteria — a "different pattern of clinical use" that makes them "less tied to a

primary service" in the outpatient setting — that CMS has articulated in justifying the exclusion of molecular pathology test codes from the packaging requirement. We strongly encourage CMS to extend the exclusion from conditional packaging to cover these protein-based MAAA test codes in the Final Rule.

Finally, CMS has proposed assigning these MAAA tests with protein based underlying analytes an "E" status indicator, designating these tests as non-covered and ineligible for OPPS payment on any outpatient bill. While we believe that all MAAA tests should be assigned to status indicator "A", there is also no policy basis for classifying these MAAA tests as "E". We believe CMS has incorrectly classified these tests, and request that CMS revise these status indicator assignments in the Final Rule.

I. Background on the Coalition for 21st Century Medicine

The Coalition comprises many of the world's most innovative diagnostic technology companies, clinical laboratories, physicians, venture capital companies, and patient advocacy groups. Coalition member labs have pioneered diagnostics that make personalized medicine possible. By understanding the molecular nature of disease, these tests allow clinicians and patients to select individualized treatment options, rather than basing treatment choices on broad assessment of what works best for a population. Our members' tests, among other things, assess cancer risk, identify productive chemotherapies, and predict the likelihood of cancer recurrence.

Given the Coalition's mission to facilitate development and commercialization of innovative diagnostics to inform important patient management decisions, we have a keen interest in the agency's CLFS payment policies, HOPPS bundling policies, and implementation of the Protecting Access to Medicare Act of 2014 (PAMA).

II. The Coalition Supports Exclusion From Packaging Policy For All Molecular Pathology Tests

Current CMS policy is to "package" certain clinical diagnostic laboratory tests in the Hospital Outpatient Department. Under this packaging policy, common and routine clinical diagnostic laboratory tests that are ancillary to the primary service, provided in the hospital outpatient setting, and provided on the same date of service, are packaged with the hospital outpatient payment instead of being paid separately on the CLFS.[1]

Previously, CMS has excluded certain molecular pathology tests from the packaging rule requirement. For CY 2016, CMS is proposing to expand the exclusion from this packaging rule to encompass all molecular pathology tests. CMS notes in the Proposed Rule that its rationale for not packaging molecular pathology laboratory tests is that:

[1] 80 Fed. Reg. 39,235 (July 8, 2015).

> **we believed that these relatively new tests may have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package. We believe that this rationale remains applicable and may be appropriately extended to <u>any new molecular pathology tests</u>.**[2]

As a consequence, CMS states that its intent is "to assign <u>all</u> laboratory tests that describe molecular pathology tests status indicator 'A' in Addendum B to this proposed rule . . . which means that they are separately paid at the CLFS rates outside of the OPPS."[3] The Proposed Rule states that "[w]hen laboratory tests are not packaged under the OPPS and are listed on the CLFS, they are paid at the CLFS payment rates outside the OPPS under Medicare Part B."

III. <u>CMS Should Exclude *All* Tests Classified by AMA CPT as MAAAs or Designated by CMS as ADLTs</u>

While the Coalition strongly supports the proposal to exclude all molecular pathology tests from the packaging rule, we also strongly believe that the stated the rationale for this exclusion — that the excluded tests "have a different pattern of clinical use, which may make them generally less tied to a primary service in the hospital outpatient setting than the more common and routine laboratory tests that we proposed to package"[4] **—** applies equally to MAAAs (and ADLTs as designated by CMS) with similar patterns of clinical use.

As such, we encourage CMS to exclude all tests that are either a) assigned a MAAA CPT code, or b) designated by CMS as an ADLT, from the OPPS packaging requirement. From both a clinical standpoint and policy rationale, it is entirely consistent to exclude tests that meet the AMA CPT definition of a MAAA or the PAMA statutory definition of an ADLT.

A. Definitions of MAAAs and ADLTs

The Proposed Rule states that the relevant tests for the exclusion from the packaging proposal are the "molecular pathology tests described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479." In addition, in Addendum B certain Multianalyte Assays with Algorithmic Analyses (MAAA tests) that are based upon DNA or RNA underlying analytes were similarly excluded. The AMA CPT definition for "Multianalyte Assays with Algorithmic Analyses," includes both DNA/RNA tests as well as protein- based tests:

> procedures that utilize multiple results derived from panels of analyses of various types, **<u>including molecular pathology assays</u>**, fluorescent in situ hybridization assays and non-nucleic acid based assays (eg, proteins, polypeptides, lipids, carbohydrates). Algorithmic

[2] 80 Fed. Reg. 39,236.
[3] Id.
[4] Id.

> analysis, using the results of these assays as well as other patient information (if used), is then performed and reported typically as a numeric score(s) or as a probability.

This definition is similar in form and scope to the newly-established definition of an Advanced Diagnostics Laboratory Test (ADLT) in the Protecting Access to Medicare Act of 2014 (PAMA). In PAMA, Congress defined an ADLT as

> an analysis of multiple biomarkers of DNA, RNA, or **proteins** combined with a unique algorithm to yield a single patient-specific result.[5]

Similar to the MAAA definition, the PAMA definition of ADLT encompasses both DNA/RNA molecular pathology and protein-based MAAA tests. In establishing the definition of an ADLT, Congress recognized that there is a new class of advanced laboratory tests that is distinct from the common laboratory tests routinely performed. A threshold requirement for an ADLT is that it is performed and offered only by a single laboratory. If CMS in the Final Rule were to apply a restrictive definition of molecular pathology tests that does not include both DNA/RNA and protein-based MAAA tests, such a policy would not apply to all tests designated by CMS as ADLTs as defined by Congress.

B. MAAAs and ALDTs Have Clinical Patterns of Use Similar to Other Excluded Tests and are "Generally Less Tied" to a Primary Outpatient Service than are Packaged Tests

CMS has intended to package clinical laboratory tests that are primarily offered and performed in the hospital outpatient setting. Many of the molecular pathology tests which have been excluded from the packaging since they are "***generally less tied to a primary service in the hospital outpatient setting***"[6] are not primarily offered in the hospital, but are sent out to independent labs for processing. In contrast to those commonly performed hospital outpatient tests and similar to the molecular pathology tests, these protein-based MAAA tests and other ADLTs are only performed outside the hospital setting at a single independent laboratory.

MAAAs and ADLTs have clinical patterns of use that are similar to the other molecular pathology tests that have been excluded from the packaging rule. Given the Proposed Rule's rationale of excluding molecular pathology tests based on a different pattern of clinical use than the "more common and routine laboratory tests," we believe that the agency in the Final Rule must similarly exclude all MAAAs and ADLTs tests from the packaging policy, and pay for those tests separately on the CLFS.

MAAA tests clearly have a "different pattern of use" from "more common and routine laboratory tests" and are "generally less tied" to a primary service in the hospital. For example, code 815XM (VeriStrat), is a predictive and prognostic serum proteomic test for patients with

[5] Section 1834A(d)(5) of the Social Security Act.
[6] Id.

advanced non-small cell lung cancer (NSCLC) that is covered and paid by Novitas Solutions.[7] The test yields a single results that provides therapeutic guidance to the patient and treating physician. Similar to several DNA or RNA-based MAAA tests, VeriStrat requires the measurement of clinically-relevant cancer biomarkers that are combined by an algorithm, except its biomarkers are clinically-relevant proteins, rather than clinically-relevant DNA or RNA. VeriStrat is solely provided by Biodesix, and like the molecular pathology and DNA or RNA based MAAA tests, has a different pattern of clinical use from routine outpatient tests performed in the hospital. The majority of oncologists who treat patients with NSCLC also treat patients with other tumor types. However, they do not order the test for all of their patients. The test is used for a niche group of patients, and is neither routinely ordered for all patients nor offered by the hospital. Following the order from the physician, the patient's blood is drawn and sent to the Biodesix independent laboratory for processing. The hospital may or may not perform the blood draw, and does not perform any portion of the test.

Similarly, Vectra DA offered by Crescendo Bioscience is the first and only multi-biomarker blood test that includes an algorithmic analysis to measure rheumatoid arthritis (RA) disease activity; it is covered and paid by Noridian Healthcare Solutions[8]. Vectra DA measures twelve pathologically relevant serum proteins together to generate a single score on a scale of 1 to 100, which represents the level of RA disease activity. Like other molecular pathology tests, Vectra DA is performed outside the hospital setting and is not generally "tied to" a primary service in the hospital outpatient setting." Vectra DA is performed only at the Crescendo Bioscience laboratory in South San Francisco, CA on blood samples collected at the request of rheumatologists, of which there are approximately 4,000 such specialists in the United States. The usual circumstance under which Vectra DA is ordered is at an office visit with a rheumatologist. The office visit for an RA patient typically entails a subjective assessment of the patient's condition through discussion of patient-reported symptoms and examination the patient's joints by the rheumatologist. On occasion RA patients may require hospitalization over the course of their disease, but their RA is rarely the reason for the hospitalization, and it would be unusual for Vectra DA to be ordered during the hospitalization.

Additionally, ChemoFx offered by Helomics, Inc. is a cell culture based chemo-response assay that measures the sensitivity and resistance of tumor derived malignant epithelial cells to chemotherapeutic agents in vitro.[9] A live tissue specimen is collected following surgery, core needle biopsy, or fluid draw, and sent to the Helomics laboratory. At the Helomics laboratory the epithelial cells from the patients' tumor are allowed to grow. They then begin cycling to allow for the testing of both cytotoxic and cytostatic drugs. Following an incubation period, the underlying biomarkers (protein and DNA) are tested.

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[7] Veristrat is covered under Local Coverage Determination (LCD): Biomarkers for Oncology (L34796).
[8] Article M00031, V61; see http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Covered%20Tests~97KMQ68675?open&navmenu=Browse^By^Topic||||
[9] ChemoFx is covered by Novitas under Coverage Article A51682.

The assay endpoint is determined by a applying a unique algorithm in the quantification of cellular material, proteins and DNA. The assay employs live tumor tissue samples available at the time of clinically indicated surgery, biopsy or paracentesis. The results of these biomarker inputs are processed by a unique algorithm that reports a result back as either More Effective, Effective, or Less Effective. The physician does not order the test until approximately 21 days after the tissue collection has been grown and is viable for testing. Then, a final report with the results of the test are sent to the ordering physician.

IV. Status Indicators For Certain Clinical Laboratory Tests Are Incorrect

Finally, our review of "Addendum B" to the Proposed Rule suggests that the status indicators for certain MAAA tests appear to have been assigned in error. The Coalition encourages CMS to review and correct these assignments in the Final Rule.

In order to implement the conditional packaging rule in CY2016, CMS has proposed a list of tests that will be conditionally packaged, as well as a list of tests that will be excluded from the conditional packaging policy. The payment status of a given test will be based on the proposed "status indicator" designation that CMS assigns to each. The list of tests and their respective proposed status indicators is contained in the online "Addendum B" to the Proposed Rule, as is an explanation of each of the various status indicator options.[10]

In reviewing the proposed Addendum B, it appears that most MAAA test codes that have DNA or RNA-based underlying analytes are proposed to be exempt from packaging, having been assigned a status indicator of "A" ("Services furnished to a hospital outpatient that are paid under a fee schedule or payment system other than OPPS"). Tests with a status indicator of "A" are tests excluded from the conditional packaging rule. As explained above, the Coalition believes that this is the appropriate status indicator for all MAAA codes.

However, instead of applying this exemption consistently to all MAAA test codes, CMS has proposed assigning MAAA test codes with protein-based underlying analytes a status indicator of "E." Tests with the status indicator "E" are those "[n]ot paid by Medicare when submitted on outpatient claims (any outpatient bill type)."[11] Addendum B states that CMS applies this status indicator to items, codes, or services "for which pricing information is not available; not covered by any Medicare outpatient benefit category; statutorily excluded by Medicare; [or] not reasonable and necessary."[12]

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[10] *Available at* http://www.cms.gov/apps/ama/license.asp?file=/HospitalOutpatientPPS/Downloads/CMS-1633-P-OPPS-Addenda-B-2-Times-Rule.zip

[11] *See* http://www.cms.gov/apps/ama/license.asp?file=/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/CMS-1633-P-OPPS-Addenda.zip

[12] Id.

The Coalition is unaware of any policy or legal rationale upon which CMS can assign the "E" status indicator to MAAA tests like those represented by CPT codes 815XL, 815XP, 815X1, and 815XM suggesting that this specific designation was potentially an administrative oversight. These tests do not meet any of the express defined conditions that CMS has indicated warrant assignment of the "E" status indicator. First, the "E" indicator is to be applied when "pricing information is not available" or when the test is "not covered by any Medicare outpatient benefit category." This is not the case here, as each such test is currently covered and paid by a Medicare Administrative Contractor's (MACs) Local Coverage Determination or published coverage article.[13] Second, far from being "statutory exclu[ded] by Medicare," these MAAAs are currently being covered and paid by MACs. And third, absent any formal (or even informal) indication from CMS to the contrary — and again, where these MAAAs are currently affirmatively being covered and paid — there is no policy basis for asserting that these MAAAs are no longer "reasonable and necessary."

We understand that assigning several of the MAAA codes to status indicator "E" is actually not a new policy. CMS assigned several MAAA codes to status indicator "E" in CY2014 and CY2015. However, we believe this assignment has been in error and reflects a misunderstanding of CMS's policy on the payability of the MAAA codes.

When the MAAA codes were first introduced for CY2013, CMS initially determined that it would not accept these codes for Medicare purposes. This determination was noted by assigning these codes to status indicator "I" ("not valid for Medicare purposes") under the Physician Fee Schedule (PFS) database. Subsequently, for CY2014, CMS determined that MAAA codes would be payable under Medicare through gapfill when the code was determined to be payable by the Medicare Administrative Contractor. With this change in policy, CMS identified some MAAA codes as status "X" under the PFS database (reflecting their status as payable under the Clinical Laboratory Fee Schedule)[14], other MAAA codes were left as status "I". Comparing the codes with status indicators "X" and "I" under the PFS database with those assigned to status indicators "A" and "E" under the OPPS database, we see a direct match. Therefore, it appears the "E" status indicator under OPPS was intended to indicate that the MAAA codes so designated were not valid for Medicare purposes (paralleling the "I" status indicator under the PFS database).

However, many of these MAAA codes are covered by Medicare and paid by the MACs and, therefore, under CMS's established policy, are valid for Medicare purposes. After receiving

[13] http://www.palmettogba.com/palmetto/MolDX.nsf/DocsCat/MolDx%20Website~MolDx~Browse%20By%20Topic~Covered%20Tests~97KMQ68675?open&navmenu=Browse%5EBy%5ETopic%7C%7C%7C%7C ChemoFx is covered by Novitas under Coverage Article A51682. Veristrat is covered under Local Coverage Determination (LCD): Biomarkers for Oncology (L34796).

[14] Status X= "Statutory Exclusion. These codes represent an item or service that is not in the statutory definition of "physician services" for fee schedule payment purposes. No RVUS or payment amounts are shown for these codes, and no payment may be made under the physician fee schedule. (Examples are ambulance services and clinical diagnostic laboratory services.)"

input from stakeholders that the "I" designator was inconsistent with CMS's policy for MAAAs and was hindering submission of claims under covered codes, CMS revised the PFS database for these codes this Spring and now all of the Category I MAAA codes are shown in the PFS database as status "X" (i.e., payable under the CLFS). Insofar as these are valid codes under Medicare, these should be identified under a valid status indicator for OPPS. As noted above, we recommend that these tests be separately payable under status "A".[15]

V. **Conclusion**

As described above, these MAAA tests have similar patterns of clinical use to those tests classified as molecular pathology tests or DNA/RNA-based MAAA tests. The Coalition believes that in the Final Rule, CMS should expand the exclusion from packaging of molecular pathology tests to include any MAAA codes or tests designated by CMS as ADLTs. Accordingly, we respectfully request that CMS assign status indicator "A" to the MAAA test codes 815XL, 815XP, 815X1, and 815XM in the Final Rule.

The Coalition appreciates the opportunity to provide comments on the CY 2016 Hospital Outpatient Proposed Rule.

Sincerely,

John W. Hanna
Chair, C21 Reimbursement & Policy Workgroup

[15] If CMS disagrees with our recommendation to exempt these codes from packaging, then the appropriate status indicator under the CY2016 Proposed Rule, would be status indicator "Q4" ("conditionally packaged tests").