

Vicky Pratt:

So, we're going to talk today about CPT coding and reimbursement. CPT code does not equal reimbursement, it's a catalog, and a list of services, and they're two separate items. I am still getting the hang of where I click. So, we're going to start off with CPT codes, and I don't know how many of you remember before January 1st, 2013, is all genetic tests and molecular pathology tests were stacked together to get reimbursed, and they were commonly called the molecular stacking CPT codes. And basically, each step of the assay, such as DNA extraction, PCR, probe, hybridization, each of those sort of steps of an assay had different CPT codes. And laboratories would put all of those CPT codes together, to create a molecular coding stack. So, what happened is, is the AMA wanted to sort of create new codes, so it got divided into -- so the new codes were called tier 1, tier 2 and Multianalyte Assays with Algorithmic Analyses, or commonly referred to as MAAS.

So, why did the AMA want to put new CPT codes together? So there was getting -- eventually it came down to payers wanted to know what they were paying for, and we needed a clear and granular system to do that. So, part of my job was to get information from laboratories throughout the country and usually, most of it involved the large reference laboratories, and some smaller and medium reference laboratories throughout the U.S. So -- and I don't expect you to be able to see this or read this, but we took all the assays and the relative percentages, and put them all together. And what you can see is that, relatively, there's about 100 tests or so that really cover about 95 to 99 percent of the tests that were performed across the country, a few years ago. So now it's probably changed a little bit, but this gives you an idea that most of the testing is done in a relatively small number of tests.

So, in the new molecular pathology or MolPath codes, the tier 1 was created to be analyte-specific codes. Those are the top 100 that are gene- and analysis-specific. And then the tier 2 codes were levels of complexity lumped together. And then, you can go to the AMA website and actually see the most current lists of codes. So the general -- so part of what we had to do was sort of create a whole new format. So in a CPT 1, tier 1 descriptor, we developed that the first part of the name would be the HUGO approved gene symbol, and then the long version of a HUGO approved gene name, and in parentheses. Gene names are in italics, so that part's in italics. The second parens includes an example of the disease, state or condition. And then outside of that it's the gene analysis and the analysis type.

So, some things about these descriptors is, I was at one place, and they said, "Well, if your disease or the condition's not listed in there, but it's related to that gene, you can't use that test." But that's not true, that the disease and condition is an E.G. statement, and not an all-inclusive list. Often common gene variant names are used, and the code includes all analytical services performed in the tests, if they're cell lysis, DNA extraction, digestion, amplification and detection. And then all the analyses are qualitative unless otherwise noted.

So just to go over an example here, is we have BCR/ABL, which is a gene fusion for chronic myelogenous leukemia. We don't-- the HUGO [spelled phonetically] is actually two genes fused together, so it's a translocation, so we're using the translocation or the cytogenetic information. And there's a translocation analysis for the major breakpoint, whether it's qualitative or

quantitative. And then there's sub-codes here, for the minor breakpoint, and other breakpoints in the fusion.

Another example is cystic fibrosis, where we have a gene that analysis at [spelled phonetically] common variance. ACOG and ACMG have some guidelines, and we didn't know if that was going to change or stay stable over time. And instead of listing that all, we just put the most of the ACOG or the current -- basically the current guidelines. Then, under C.F. [spelled phonetically], you could test for known familial variance, the links in our duplication, full gene sequences, and in some cases -- when fertility, just for the poly T analysis, in addition to cystic fibrosis. The array CGH is also commonly performed, and at that time a lot of the Array CGH codes were oligo or BAC. I think that's mostly gone away. Most people are now -- most laboratories are now doing the 81229 for the copy number and single-nucleotide or SNP variance arrays. Oh, we did put language in there that you couldn't use both of these at the same time. So either one or the other gets used.

In tier 2, at the time we had approximately 600 different genes or gene-type analyses to be divided up. And these were sort of that long never-ending tail of that graph I showed you earlier. These tests are most commonly performed, but they still need tier 1, or, I mean, Category 1 status. They're lower-volume assays, so these were divided into nine levels of complexity. So for the tier -- so just to give you an idea, I'm not going to -- and there's examples underneath all of these, is that tier 2 level 1 is basically one variant or one SNP testing. tier 2 is two to 10 SNPs, or a methylated variant, or a somatic variant. Somatic or tumor testing, or -- oncology testing is usually much more complicated than a single DNA blood test. So that had a little higher level of complexity. Then there was greater than 10 SNPs, for tier 2 level 3. In level 4, this is where we start doing sequence analysis, so this is analysis of a DNA sequence of a single exon, or if you're using some sort of multiplex analysis of 10 or more exons. Or 10 or more variant reactions.

In level 5, we're doing sequence analysis of two to five exons, and really most of this was developed before the advent of massively parallel or next-generation sequencing. Then we have six to 10 exons in level 6, 11 to 25 exons in level 7. And this is by the number of genes-- how many exons it simply has. Level 8 is 26 to 50 exons, and then in level 9, it's greater than 50 exons. And actually there's very few genes that actually fit into level 9. So some of the questions that came up during this is, "What do you do if your favorite gene's not listed?" So, there is a miscellaneous code called 81479. So at the time, during the conversion, a lot of labs said, "Well, my favorite gene fits in this level." And part of the requirement is that you can't self-assign. If your favorite gene's not in a level, then you have to submit a coding change proposal. There's so much --

Female Speaker:

Excuse me. We can't get into the WebEX and see the slides. We don't have the [unintelligible].

Male Speaker:

There's a password.

Female Speaker:

The meeting password is the word “Genetics,” with a capital G.

Vicky Pratt:

All right, I’m going to continue.

Female Speaker:

Success. Thank you.

Vicky Prat:

All right, so part of the rules of the road is that you can’t use multiples of 81479, because some of the labs said, “Well, I’m doing lots of genes that aren’t in that list. Can I use multiples?” And the answer to that was no. So if your favorite gene is not in the list, then you can submit a coding change proposal. And that’s available on the AMA website, and you have to be able to reference -- have reference to document the clinical validity of that gene, and with that disorder. You have to draft -- in your submission, you include a clinical vignette and a description of the service.

So here’s an example for BRAF, which is a gene test for colorectal carcinoma. And the common variant that’s usually tested, which is V600E. So in a clinical vignette, a 54-year-old man with metastatic colorectal carcinoma is being considered for targeted therapy, with an EGFR monoclonal antibodies, initial molecular studies indicate the tumor does not contain any of the 12 common KRAS mutations. And the tumor-rich sample is accepted [spelled phonetically] for BRAF testing. And then, in a description of service -- and this is the most common description of service, or the most likely description of service. Paraffin is removed, DNA is isolated, there’s PCR for the BRAF gene. It goes side-directional. Sequencing, and capillary electrophoresis, and pathologist or other qualified healthcare professional evaluates and provides a report.

So once we get a CCP at the AMA, we look at it to determine the parameters for analyte assignment. So, in the Mendelian somatic disorders, we look for a demonstrated relationship between the biomarker and the phenotype. In other words, does it have clinical validity? Do the biomarkers or the SNPs that have an association, but not proof? This is more the GWAS type of assays, or studies that have not a proven cause-and-effect to the known clinical phenotype, but should have demonstrated clinical usefulness, whether that's -- such as a high-positive predictive value, or a high-negative predictive value directing therapy and management.

We did require at least two U.S. laboratories to perform the analysis, unless it was proprietary or intellectual property issues existed. That was prior to the Supreme Court decision against Mariette a few years back. Analyses involve greater than 10 variance for unrelated family, so we’re looking for tests that -- not the super-super-super rare stuff, but something that you see in multiple unrelated families to prove clinical validity. And then for the duplication-deletion assignments in the tier 2 code, not all duplications and deletions got assigned an analysis. It had to be greater than 10 percent of the disease alleles [spelled phonetically] associated with duplications or deletions. We did use professional databases to verify all the information for code assignments.

So then, NGS came along while we were in the middle of this entire process, and then labs started doing multi-gene panels. So the Association for Molecular Pathology submitted a coding change proposal to put multiple genes together into gene panels. So they were quantitative genomic sequences -- So some of it included exon testing, and whole genome-- I like how I said "genome genomic sequencing testing." It's supposed to be a whole genome sequence analysis. It included the report and interpretation -- separated the report and interpretation from the analyte, and this is the first time that we did this in the MolPath coding set. And that was because, at least in whole genome and whole exome testing, that you may have to go back and re-analyze the data for a different genetic disorder or a different indication. So, and there is a fair amount of work with reanalysis. I wanted to be able to code for that. So the AMA had multiple open meeting -- or at least one open meeting to discuss this with key players, or anybody who wanted to come, and developed the new codes, which are actually in the 2015 CPT coding book.

So here's an example of the new ones that were created. There was an aortic dysfunction, non-syndromic hearing loss, intellectual disability, inherited colon cancer, fetal chromosome aneuploidy, which is for the non-invasive prenatal testing. We had targeted neoplastic genomic sequences. There's a lot of -- there was a lot of -- nobody was happy with the descriptors when we got done. When we were working on this, I think my email blew up at least four or five times, with people making recommendations and suggestions on the neoplastic genomic sequence procedures. And then there was a whole mitochondrial, whole exome and a whole genome. The MAAA codes, CMS announced that the MAAA codes will be gap-filled, if the Medicare contractor determines that the code is payable under the clinical lab fee schedule. So, in the most recent clinical lab fee schedule, there's multiple MAAAs that have been -- some of them have been cross-walked and gap-filled, and we'll talk about reimbursements.

So, I always get this question, "Why didn't each gene get its own CPT code?" And the answer is, simply, there's not enough numbers in CPT to do that. At the AMA, it did -- we did recommend that the gene symbol, the HUGO gene symbol, the HUGO gene name be added as a descriptor, especially for the tier 2 codes. And then, another question I often get is, "Well, can a code be moved from tier 2 to tier 1?" And yes, and that has to be requested by a coding change proposal, and approved by the AMA. And actually, in the 2016 book, or maybe it was even in the 2015 book -- actually I think it is in the 2015 book -- there are multiple codes that were actually moved from tier 2 to tier 1.

So, I'm going to talk a little bit about reimbursement, or the pricing process that CMS goes through. I don't know how many people are familiar with that or not, but to give you an idea of what CMS does. So, actually the new CPT codes were available -- the new MolPath code set was available in the CPT coding book in 2012. But at that -- there was really no price or -- there was really no price associated with the new codes. So nobody -- so labs didn't really want to use them, or start using them. So during that sort of that 2012 -- that sort of transitional year between 2012 and 2013, when the old stacking codes went away, there was a sort of fight to determine whether the labs go -- or all those new codes go on the clinical lab fee schedule, or the physician fee schedule. And the background on that is that all the stacking codes were on the clinical lab fee schedule, but the RUC, which is the Specialty Society Relative Value Update Committee, recommended that all the new codes go on the physician fee schedule. So when you looked at that, there's federal laws that are related to physician practice, whether it's MD versus

PhD, co-pays, anti-kickback rules, and physician signature requirements. So CMS decided to place all the new codes and the tier 2 codes on the clinical lab fee schedule.

So, if you're looking at physician practice, whether it's physician fee schedule or clinical lab fee schedule, actually in federal law, for physician pathology services, the carrier pays for pathology services furnished by a physician, to an individual beneficiary on the fee schedule basis only if the services meet the following conditions. Whether it's a Surg-Path service, a specific cytopath, hematology or blood vacuum services, a clinical consultation service, and clinical laboratory-interpretive services that meet the requirements. Part of the issue between this is whether, sort of, the fight between MDs and PhDs in reviewing MolPath tests. So a lot of this is done by PhDs, and not by MDs, so it was sort of a fight between MDs versus PhDs.

So if the codes would have gone on the physician fee schedule, labs would have been required to collect a 20 percent co-pay. At this time, everything on the clinical lab fee schedule, there are no co-pays. So this would have been something completely new for laboratories to do, and not to say, not some time in the future that labs may have to do co-pays, but this is not something that's currently being done. There's also special signature rules that are not required of clinical laboratory tests regarding physician kickback and purchasing for clinical laboratory tests. Pathology tests are paid on a different and much lower fee schedule, in the outpatient setting, than they are on the clinical lab fee schedule. And then indirect costs would be assigned on the basis of all pathology indirect costs and hospital costs.

So, because there was a concern around physicians not being able to -- who do actually review and sign out the MolPath test codes -- the MolPath test codes, CMS did create a HCSPCS code called GO452, for the 2013 code book. And this allowed physicians or MDs to bill for the interpretation reporting services that go beyond the technical reporting of the tests. It cannot be billed by non-physicians, geneticists or other lab personnel. And in 2013 -- and I'm not sure that it's changed at this time, it was reimbursed at \$18.71 per test.

So, for all the test codes, CMS has two methods to determine reimbursement. One is crosswalk and gap-fill. And I have to tell you, I was not that familiar on gap-fill before MolPath happened. So for cross-walking, if the test is comparable to an existing test, CMS sets reimbursement of the new test to the existing test, and then it's assigned a local fee and corresponding National Limitation Amount. So while everybody was fighting in 2012, when the new MolPath codes were in the CPT code book along with the stacking codes, CMS could have cross-walked the stacking codes to the MolPath codes. But there was too much fighting whether it went on the physician fee schedule or the clin-lab fee schedule. So it wasn't cross-walked at that time.

So, in 2013, then, because they were new codes, then CMS determined that they should be gap-filled. And in gap-filling, CMS determines that there's no adequate comparable. Before the new MolPath code set came along, and it was around a 110, 109 CPT codes, the contractors had never done that many gap-fills at one time. So, when Medicare carriers or contractors are instructed to gap-fill, it's an empirical process based on local pricing patterns. And the medical directors among the contractors can meet and share information, but they can't reach consensus. Gap-filling actually takes -- the process takes about a year, so up to -- so basically during the first three months, the contractors get the amount, and around then April -- around April 30<sup>th</sup>, CMS

posts an interim contract-specified amount online. It allows a 60-day -- by law, you have a 60-day comment period on the interim amounts, which is essentially May and June, and then CMS posts the final contractor and limitation amounts online, like mid-summertime. Usually it ends up being around August. Then it allows for reconsideration for about 30 days, which goes into October-ish timeline, and then the final national limitation amounts are made effective January 1st, for the entire country. So it's a long process to get that value.

I'm not going to go in this in too much detail, but what I've provided more for your information is that -- so here's the gap-filled tier 1 codes, but if you're really super familiar with the MolPath CPT codes, there's actually genes missing. So one of the genes I had mentioned previously was cystic fibrosis. Cystic fibrosis is not in the tier 1, it's not in tier 1 here, along with some various other genes. And that is because primarily cystic fibrosis does not affect the Medicare population, or the 65 and over crowd. So CMS didn't set a price for cystic fibrosis and various other codes in the MolPath code set, tier 1 code set.

So, just as sort of an example. Again, more of the codes. We have some Lin Syndrome codes, more Lin Syndrome, TMB cell gene rearrangements, and HLA tests, HLA. So in the 2015 book, as I mentioned previously, the genomic sequencing procedures -- AMA created the genomic sequencing procedure code or the GSP codes. And all of 2015, CMS has instructed the contractors to gap-fill those. And that process actually was just, I think -- last week, CMS announced the -- and this was prior to giving this slide set to Blue Cross. Last week CMS just announced the gap-filler rates for the GSP codes. So, for your favorite area in the United States, where you are, I'm here in Indiana, so my Medicare contractor is Wisconsin Physician Services, and then -- and so -- and then I have a nice -- this was the most recent chart of the regions that the Medicare Administrative Contractors cover. This does change at times, depending on the contracts. The contracts are renewable, it does change over time.

So just sort of in summary, if many of the MACs in the gap-filled rates seem to have coordinated their gap-fill rates for MolPath, though some of the MACs such as Palmetto have established rates for all the codes including tier 2 codes, but CMS did not include them in their release. I do know that I just saw a local coverage decision proposal from WPF for some tier 2 analytes, and this is one of the first contractors I've seen do tier 2 descriptors, besides Palmetto. CMS hasn't finalized any reimbursement for any of the tier 2 codes, and each individual Medicare contractor will continue to establish pricing for that. And I don't know -- I'm sure for Blue Cross Blue Shield, as well as the MolPath community, the complete revision has had a huge impact on reimbursement for molecular pathology. And that is the end of my talk.

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