



April 14, 2022 and May 12, 2022

Haystack Advocacy Empowerment Initiative (AEI) Speaker Series
Beth Roberts, Partner, Hogan Lovells
The What, When, How... and *IF* of ICD-10 coding

Beth Roberts, Partner, Global Regulatory practice, Hogan Lovells. Hogan Lovells is one of the ten biggest law firms in the world and one of the biggest lobbying firms in the US. We were honored to have Beth speak with us in April. Beth helps clients navigate complex coding, coverage, and reimbursement challenges facing new technologies. She also counsels clients about the intricacies of Medicare and other healthcare issues. Our conversation was largely about ICD-10 codes.

Patient groups shared their experiences with Beth, and we delved into the specifics of how to apply for an ICD-10, how to evaluate whether an ICD-10 is a good idea for a particular group of patients or a condition, and the nuances of judging the pros and cons of codes primarily used to process insurance claims.

Given the extent of patient group interest, we replayed the session in May, taking the time to further parse Beth's counsel, and evaluate specific examples from the perspectives and motivations of patients, their providers, researchers, manufacturers, and yes, even ICER! (ICER's recent report on rare calls for more ICD-10 codes.) We asked 'why' each stakeholder may be for or against ICD-10 codes for rare conditions, how they may use them, and how those reasons impact patients.

The Basics.

Beth started by explaining the two kinds of ICD-10 codes:

1. ICD-10-PCS procedure codes (that describes procedures performed, and are often used in the inpatient setting to process "new technology add on" (NTAP) payments).
2. ICD-10-CM diagnosis codes.

Helpful to know/understand both. A new drug may also get a PCS code to facilitate an NTAP to allow for additional payment in the inpatient setting.



HAYSTACK PROJECT

The Voices of Rare & Ultra Rare



What ICD-10 CM Codes Do. Beth then explained that in addition to being used for epidemiological purposes, these codes are used to process insurance claims. In other words, these codes guide an insurance company's decision whether to cover/pay for a drug, device, or procedure for a particular patient. And, correspondingly, how much to pay for it. A doctor's decision to prescribe or administer a drug or undertake a procedure for his/her patient based on their evaluation of the patient and their medical condition is *not* the decision an insurance company relies when making a call on (a) paying for it and (b) how much to pay for it.

The insurance company makes that evaluation on its own, and the ICD-10 code informs their decision. Drugs, devices, and procedures are only covered for patients with certain diagnoses, and those diagnoses are listed, by their ICD-10-CM codes, in the insurance company's coverage policies as covered because they are deemed "reasonable or necessary" or "medically necessary" for that diagnosis.

On Label vs. Off Label.

When a drug is approved by the FDA, the drug gets a "label," which specifies what conditions the drug can be used for. These labels can be quite detailed, even specifying things like the stage of cancer the drug can be used for, whether the drug can be used first or only as a second or third treatment option. The label can be limited to use in a subtype of a rare disease too. When used/prescribed in these ways, the use is called "on label."

Once the drug is on the market, doctors may discover the drug works well in a different subtype, in a related disease, or best if used first instead of second. These uses are called "off label."

Doctors can use/prescribe a drug for "on-" or "off-label" uses, but insurance companies may not pay for an off-label use.

One group asked if a more specific code would allow an insurance company to force a patient to take an on-label drug when he/she is stable on an off-label drug already. Beth explained that while there are appeals mechanisms, peer-to-peer processes, etc., all that is hard, fighting every step of the way with every prescription renewal. We also discussed the flip side when the on-label treatment is the perfect option for the patient, but a granular ICD-10 code won't



HAYSTACK PROJECT

The Voices of Rare & Ultra Rare



guarantee your insurance company will pay for it without first forcing the patient to try other treatments. In other words, the very specific rare disease code is not a magic bullet to go on or stay on the right treatment for each patient.

Example.

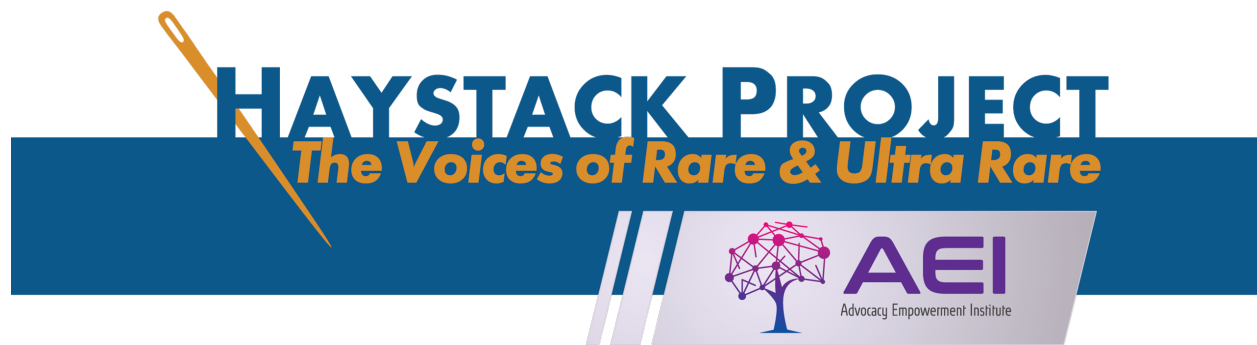
Beth shared IVIG and steroids as two examples of drugs often prescribed off-label for lots of different conditions. Asked if a patient has a really rare disease with no specific ICD-10 code, is it easier or harder to get the IVIG in Beth's example – the answer it's often easier. Providers look at the coverage policy and the patient, and may be able to code the claim they submit for processing by insurance in such a way that identifies that compromised immunity of the patient, therefore needing IVIG. When a more specific diagnosis code exists, and that patient's rare condition is not on-label because IVIG was not specifically studied documented in that rare condition, and IVIG's coverage policy has not been opened up and edited to include the new specific ICD-10 code, it will be harder for the doctor to explain his/her use of IVIG for the patient such that it will be covered by insurance.

Rare disease patients often use different drugs with coverage policies where the specific rare diagnosis code is not listed. This is the case not just for treating the primary condition, but also oftentimes for drugs used to manage symptoms or side effects.

Pros/Cons.

A patient group talked about their cholestatic liver disease, with some stakeholders wanting a specific ICD-10-CM code and others discouraging the patient group from moving forward. She shared various components of the disease, the symptoms that need managing, and the difficulty patients are already facing to pay for needed treatments for the various manifestations.

This example gave the group a chance to highlight that the lack of a very specific ICD-10 code does not mean there is no code for a patient seeking care. The care sought/provided will be documented on a claim submitted for payment based on the doctor's seeking out the most appropriate code for the circumstances. A code is in fact used, the claim is processed, and the insurance company decides whether or not to cover and pay for the treatment. This happens every day now without the push for more granular/specific rare disease codes.



Beth reiterated that all health care providers must code to the greatest degree of specificity available to them. Putting a more general code on a claim to get something covered for a patient when a very specific rare disease code exists could make a doctor liable under the False Claims Act, potentially resulting in jail sentences, liability, damages, etc. This is what makes these issues so sensitive, difficult, and carry such high stakes.

Current Efforts.

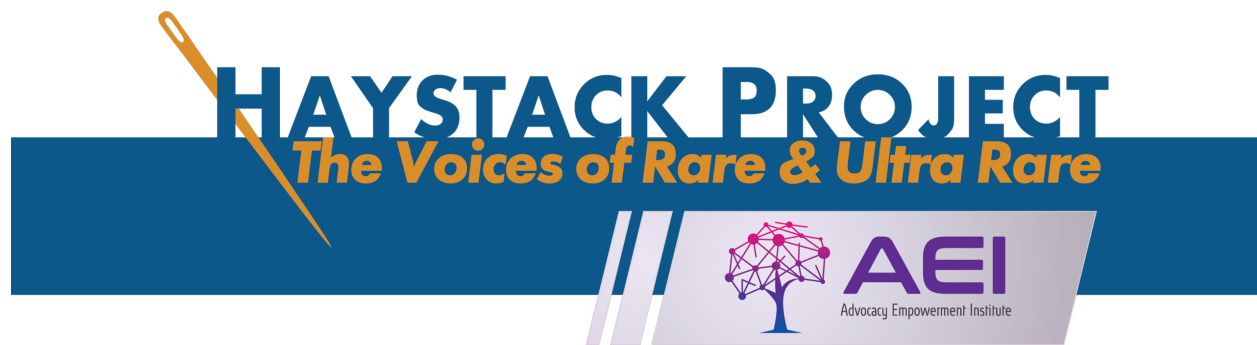
Beth noted she is seeing a push right now to get a diagnosis code for really rare conditions, almost as a rallying point for identification, recognition, or even validation of a rare disease, and a hope to accelerate research.

In some ways, the long diagnostic journeys our patients face makes us even more susceptible to “wanting a name for what we suffer from,” to prove “it’s not all in our heads,” as so many of us experience. And a code to go with that name seems a logical extension of that. This desire is multiplied when we hear a code may help us find more patients like ourselves, may facilitate research and clinical trials....

Beth noted that oftentimes rare disease patients, when seeking care for example in an inpatient setting, are not supposed to have health care providers discriminate against certain diseases. But we have seen bad actors who see a patient’s diagnosis and they want to tell patients to go to a different hospital, go to a specialty care center, etc. While not blatant, the patient’s diagnosis code can signal, not just to insurance, but to a hospital, that the patient will be costly to the facility, because their reimbursement will not match the costs of caring for that rare disease patient. Patients feel like they’re passed around and feel like they can’t get treated.

Nuts and Bolts.

Asked to describe the process of getting an ICD-10 code, Beth noted the process is pretty straightforward as far as coding applications go. Procedure codes are handled by CMS, while diagnosis codes are handled by CDC, specifically the National Center for Health Statistics. Applications are submitted by email, and there is not a set application. Instead, the applicant simply has to describe the code requested, the rationale, and supporting clinical references and literature. Beth recommended submitting peer reviewed literature instead of assuming CDC would have/find it. She also noted the need to do one’s homework in talking with KOLs to



understand the downstream consequences, and talking with any related diseases for impact. She explained there are two ICD-10 meetings a year (Spring and Fall), and applications must be received a few months in advance of each meeting.

A couple of patient groups outlined their experience with this process, and expressed frustration at their denials. Beth said reasons for denials can vary. Typically, diseases where there's a dispute in the medical community about what is causing the disease, what the disease is, is it observational, genetic, etc., means CDC will hesitate. Beth recommended having KOLs, those who have published about the disease, how its diagnosed, etc. should help. From CDC's perspective, they are fearful that patients will be misdiagnosed, that where they put the code in the code book may be confusing or wrong because we're still learning about the disease; These factors can create challenges, whereas the CDC wants broad consensus and not ongoing challenge as more is learned about a disease.

Beth reiterated the tension between diseases not yet well understood, getting a code, and the downstream impact on a patient then seeking care when a new treatment comes to market. The code we wanted for electronic health record tracking, research, etc. is now not in the insurance company's coverage policies for that treatment, so from a coverage/payment perspective, it can be a concern. Same can be said for when codes characterized by one set of parameters are in place long before a treatment comes to market and the label eventually comes with different parameters. While not rare, we used Alzheimer's disease as an example for clarity, where codes relate to early and late onset while a drug's label addresses use for mild, moderate, or severe disease, putting an insurance company's decision to cover the treatment in limbo.

Recourse for Denial of ICD-10 requests.

Another patient group asked about how to appeal or litigate when turned down for a code. They thought a granular code would speed repurposing of drugs, and were less focused on the fact that their patients were already taking off-label treatments. It is important to be aware of patients' insurers, related coverage policies, and the common treatments your patients are getting. Weighing that against the need for a code in an important first step. For both this step, and for addressing the CDC denial, Beth recommended working with the clinicians and KOLs that care for your patients every day, fighting with insurance companies on their behalf. She also advised to talk to CDC staff, and ask them for more input. And finally, she noted that



HAYSTACK PROJECT

The Voices of Rare & Ultra Rare



AEI
Advocacy Empowerment Institute

as important as the doctors are to the CDC, the coders are critical. She suggested going back and watching the discussion and the Q&A, all of which is recorded, for insight into next steps. While there is no clear appeals mechanism, working with the staff and other interested stakeholders to get to a good outcome is the best course.