

Medical Necessity Webinar Series Part 1 - Define and Discuss the Use of Evidence to Form Medical Necessity Criteria and Policy

Questions and Answers on the Live Webinar

I respect payers' decision about sticking to the evidence-based framework, but since it is so challenging to have high-quality evidence for such a quickly evolving field, would payers' policy be lagging behind the clinical practice?

Answer shared on webinar: Great question! I think payer policy based on a wealth of evidence will always lag behind clinical practice. That is something payers point to as a positive in many areas of medicine, such as procedure or device management because harms are mitigated. But I challenge this framework in the application of genetic testing, where risks are few and concern for overuse/psychological harm are not borne out in literature. So, I agree a much more adaptive policy framework would be better!

Do you also consider recommendations provided by NCCN especially for microarray testing in hematological cancers?

Answer shared on webinar: NCCN guides most payer policies, generally. It takes a lot of evidence for harm or inconsistent evidence to depart with NCCN. Always good to show what evidence is used in NCCN decisions, not just citing NCCN. Some payers/benefit managers view NCCN as "the loudest person on the call decides" vs. evidence based, so I always tried to highlight the studies instead of just relying on NCCN.

How often is the evidence reviewed to update payer policies? For example, what is the lag in getting the ACMG clinical practice guidelines incorporated into payer policies?

Answer shared on webinar: Depends on payer but each payer publishes the process and timeline.... often once or twice a year. I can't stress enough how helpful it is for providers and societies to proactively send new guidelines that would change a policy! Ask for time to review! Some medical directors will listen!

You mentioned ACMG evidence based guidelines, do you see as evidence from Cancer Genome Consortium (CGC) recommendations and guidelines for microarray testing in various cancer types, liquid and solid?

Answer shared on webinar: I am not sure how many payors are considering CGC recommendations. As a genetic counselor in oncology, I have found many payors do not cover liquid biopsy, tumor testing, but some payors do.

It seems to me that the issue isn't the exact type or level of evidence, but the misalignment between what clinicians would consider adequate evidence to guide care and what payers consider adequate to justify coverage. Increasing the amount of evidence would be great, but in the shorter term it seems like there needs to be some sort of meeting of the minds so that care and coverage are aligned. How can genetics professionals and payers get on the same wavelength?

Answer shared on webinar: Such an important point! We don't have the evidence not because Genetic testing isn't helpful but because it is hard to capture. Payers and policy writers with genetic expertise seem to be adapting better in this dynamic. More genetic providers at Payers!!! and in your practice, if there is a particular policy that is really hurting patients, see if your institution can advocate to the medical director.

Agree that randomized controlled trials (RCTs) are the gold standard in many domains as an evidence source. As Julie mentioned there are limitations. Could payers reconsider the RCT in the context of advanced cancer, where there may be significant ethics at play — for example, a comparator group may be randomized away from a covered benefit (e.g. somatic tumor profiling) for an RCT.

Answer shared on webinar: Oh how do I wish! I think Health related QoL studies and NCCN are better surrogates for RCT. But in tumor testing, we've got RCTs out the wazoo showing panels help patients, and still the coverage is only for NCCN biomarkers, not a whole panel. So, I wonder where the definitions may be resolved.

Who should pay for the studies that aim to provide more evidence (for example, moving from short-term RCT to studies measuring long-term endpoints)? How do we balance the need to provide the best available care and the need for more robust evidence?

Answer shared on webinar: Payers might say labs should pay for a study showing their panel has clinical utility.... I personally think that is not realistic. If the biomarker/gene is valid to give a diagnosis (should be proven in literature as having caused disease), and a lab shows they can reliably detect it (AV and CV) that should be all that is needed for coverage, IMO. The BabySeq, MilSeq type projects are amazing, but very expensive, so I am not sure how this friction gets resolve. I loved the Hemophilic Utilization Group Study - an amazing series of papers showing the cost and impact of a genetic disorder and diagnosis in a way that would be really approachable to payers.

Is there a way to review a patient's specific plan ahead of time? It seems like it [would] save a lot of time [to] directly address the payer policy rather than trying to guess at the payer's medical necessity criteria?

Answer shared on webinar: Stay tuned for next webinar! But yes, I'd recommend getting policies for the 5 most common payers and 5 most common tests at your practice and

becoming aware of them. And in my teaching at GC program,, I never assign an LMN without giving students the policy first.... its WAY more impactful to write a LMN according to policy.