

# Moving the Needle: Expert Insight on the Managed Care Implications of a Growing Heart Failure Treatment Armamentarium

A Q&A With Jaime Murillo, MD



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**AJMC®:** What are the current unmet needs in the management of heart failure, and can you describe your impressions of the current treatment landscape?

**MURILLO:** In terms of unmet needs, I think it's clear that, despite the effort that many institutions have made over the past 10 years to decrease admissions to the hospital due to heart failure, the need is higher because people are living longer and have a higher number of comorbidities associated with heart failure. As a result, the spending in heart failure continues to rise as a whole. That is due to both treating the heart failure per se and treatment of associated comorbidities such as kidney disease.

Having said that, I think that the unmet needs are related to the question of whether we find a way to stabilize patients with heart failure, meaning: Can we improve their quality of life [QOL]? Can we reduce heart failure admissions? Can we decrease mortality? In advanced heart failure, the mortality can be as high as 20% to 30% in 1 year and 50% in 2 years; that is still very high.

QOL is another issue. I think we have seen results of improved QOL, but if you look at it from the patient standpoint, QOL is as important as, if not more important than, how long you live, so that's another area where I think there is a significant opportunity.

The other one is: How can we anticipate the potential of worsening heart failure? That's an area where I think the secret is to become more granular in terms of heart failure. "Granular" means not everyone with heart failure should be treated the same way, and that's the key part. What are the types of heart failure, and what are the stages of heart failure in which a specific intervention can be most effective?

**AJMC®:** How important is it to view heart failure on a spectrum and customize care rather than approach management more broadly?

**MURILLO:** The results are still less than ideal, and that's because there's a general tendency to think of "1 condition, 1 management." We talk about 5 or 6 different lines of treatments for heart failure, and people think of staggering those different types of treatment, but the "how" to do it is not clear. There is a need to tailor the therapy to the patient, and that's where I think we have not achieved the results that we can all accept.

In several ways, treating patients with preserved heart failure is different than treating patients with reduced ejection fraction. Within those with reduced ejection fraction, there are additional differences between those who have valvular-related cardiomyopathy, those who have hypertensive-related cardiomyopathy, those who have associated pulmonary hypertension, those who have ischemic cardiomyopathy, and so on. Among those with preserved ejection fraction there are several groups that may behave differently depending upon the etiology as well.

The reality is that we need to do a better job of tailoring the therapy to the particular patient. In addition, we need to identify those at high risk of developing heart failure and also those with an existing diagnosis who are at risk of exacerbation.

**AJMC®:** What are your impressions regarding how approaches to worsening heart failure have changed and how the evolving therapeutic landscape might affect this area going forward?

**MURILLO:** There has been work around determining who is at risk of going to the hospital or an ED [emergency department], or, at the very end of the curve, pretransplant consideration, often focusing on the so-called persistent superutilizers. Even within that group there are 2 or 3 different types of subgroups that are very complex. Then we have the predictive modeling, which is for those we watch closely with the goal of preventing them from going to the hospital, but the question is whether that is going to be enough.

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The next step, one of the topics we need to address, is: What is the right combination of therapy for the patient? That's where I would argue that it's not about standardizing care, but it's about identifying the right therapy for this group of people without having to “fail” one therapy before moving on to the next one. We have the mindset that someone needs to fail therapy before moving on to the next step. Identification of the best approach to a particular set of patients is going to be the key instead of waiting 3 or 6 months before they can move to another therapy. If you're not bold in thinking how to develop this approach, we're not going to move the needle.

**AJMC®:** What do you think it's going to take to move in that direction, where patients are matched to mechanisms or therapies based on specific patient and drug factors?

**MURILLO:** We recently had this conversation at one of the Heart Failure Collaboratory meetings. We can name

5 or 6 lines of therapy. What is the right combination? When will we say it's right to go to the next one? Part of the answer is to link a particular mechanism of action to the underlying pathophysiology. I truly believe it's not about boxing all the heart failure patients in the same category and saying this group of medications worked for them. It's really about this particular medication works better for this particular subgroup of patients with heart failure. If we can demonstrate a direct correlation between the pathophysiology of the heart failure to the medication, I think that's going to be a win-win scenario, and I am not talking about just removing fluid. As we know, diuretics are not significantly associated with improved hard outcomes. Finally, to get to that point, we may need additional research that includes bio- or genetic markers.

**AJMC®:** What are some of the key variables that affect formulary decisions when it comes to looking at trial data or other factors?

**MURILLO:** Formulary decisions are very regulated, and when you add the word *regulatory* to anything, you're adding, almost by definition, the words *conservative approach*, because nobody wants to make decisions that could affect large populations that are not based on what is traditionally known about that concept. You have to have the traditional medications in place, which is, interestingly enough, one of the comments made about trials. People say, “This trial didn't have enough  $\beta$ -blockers” or “This trial didn't have enough ACE inhibitors,” but before you actually design a trial for heart failure, that medication has to already be generally accepted as the traditional management and has already proved to be beneficial. Then you have the challenge of adding benefit to the already demonstrated benefit.

From the formulary standpoint, that's where you are going to see the same approach, which is, if the designed trial was done taking into account that most patients were on the traditional  $\beta$ -blockers for instance, then and only then can you say, “This is what the next line of therapy would be.” Trials such as PARADIGM-HF [NCT01035255], DAPA-HF [NCT03036124], and VICTORIA [NCT02861534] represent an additional step in the overall therapy approach, where they may find a more appropriate population. Now, that could change, but I don't expect that to happen anytime soon, unless we can go deep and have that translation from the bench—obviously without bypassing the clinical side—to the population health. That may take some time. Thinking about the future, I think there's a lot about cardiovascular disease, in general, that we don't know. We've been working on it for decades. But I expect there are things that will be discovered in the coming years.

**AJMC®:** How do newer trials, such as DAPA-HF and VICTORIA, address the need to move heart failure treatment to the more granular approach that you mentioned earlier?

**MURILLO:** The health care environment is moving toward a treatment that is mostly outpatient. The goal is that hospitals should be reserved for those who are the sickest. The COVID-19 [coronavirus disease 2019] pandemic has brought that mindset up front, and we need to be very mindful about the true need for hospitalization. Thus, the question becomes: How can we advance therapy to the outpatient environment?

For heart failure, the question isn't so much "How can we give IV diuretics in the outpatient environment?" We want to get beyond that, and that's where the newest approaches can make a difference. Can we provide therapy that will stabilize those patients, prevent them from going to the hospital, prevent them from requiring intravenous diuretic therapy, even in an emergency department or outpatient infusion facility, or office infusions? Can we make them stable enough? How many of those can we prevent from advancing to stages of significant concern? That's where there is a big opportunity, an unmet need: maintaining

people out of the hospital so that they are stable enough and that their heart failure won't progress.

**AJMC®:** As you look to the future of heart failure treatment, what key measures should be taken to ensure that we can move that needle and optimize care for patients?

**MURILLO:** The constant granularity and differentiation of heart failure with a specific target therapy—that is what is going to make the difference. To that end, there is a significant need for payers to work more closely with investigators, researchers, clinicians, and medical societies. That's something I personally have made a concerted effort to do because, at the end of the day, it's not about who pays for what. It's about understanding the real benefits of the therapies we're using. If we can work together to find where the real benefit is located, we can work together to find where this benefit is the highest, and we need to move health care from a transactional experience to a more collaborative experience that, at the end, benefits the patient. Managed care organizations must commit themselves to being part of that transformation beyond the transactional role. ♦