PREVENTING DIABETIC AMPUTATIONS REQUIRES MORE THAN TECHNOLOGY

A Framework for Accurate Financial Outcome Measurement in Value-Based Care, with a Focus on Preventing Diabetic Foot Ulcers

PREPARED BY

Andrew Mackenzie, FSA, CERA, MAAA, Arbital Health
Jon Bloom, MD, CEO and Co-Founder, Podimetrics
Gary Rothenberg, DPM, CDCES, CWS, Director of Medical Affairs, Podimetrics

This white paper outlines a framework for accurately measuring financial outcomes in value-based care (VBC) arrangements, with a focus on preventing diabetic foot ulcers (DFUs). We have created a general framework for accurately setting a target price in a value-based care (VBC) deal that also enables appropriate outcomes measurement when it comes to detecting and preventing DFUs. Using this specific DFU detection and prevention program as an example, we explore key considerations and challenges to accurate measurement of financial outcomes in VBC arrangements.

podimetrics

Cracking the Code: Accurate Outcomes Measurement for Effective Value-Based Care

VBC plays an important role in advancing the Triple Aim of healthcare — improved care, lower costs, and better population health — by incentivizing providers around economic and quality improvements. However, a main challenge with VBC implementation, decision-making, and the distribution of surplus gains centers around measurement of outcomes. Can VBC work effectively if outcomes are not measured accurately? We contend that accurate outcomes measurement is critical to successful VBC deployment and is also currently fraught in practice with material issues across the industry.

Measuring financial expense, medical loss ratios (MLR), utilization, and quality outcomes for a total population, or a PCP-based attributed population, is much simpler than measuring outcomes for a high-risk, disease-specific population. Yet even total population-based VBC models can be quite complex, as indicated by the hundreds of pages of financial measurement documents for the Medicare Shared Savings Program (MSSP) and ACO REACH CMS models.[1,2]

The main difficulty lies in the fact that financial performance measurement can rarely be measured by a randomized control trial like those that are used in drug trials. Instead, an accurate measurement approach must predict what would have naturally occurred for the population receiving the intervention. This can be done using a historical control, as is done in MSSP and ACO REACH, or a concurrent control. The historic control requires an adjustment from the historical period to the current period to account for cost trends and changes in population and risk mix. Meanwhile, a concurrent control requires data on a matched population that has very similar characteristics to the studied population but does not have access to the same intervention that is being studied.

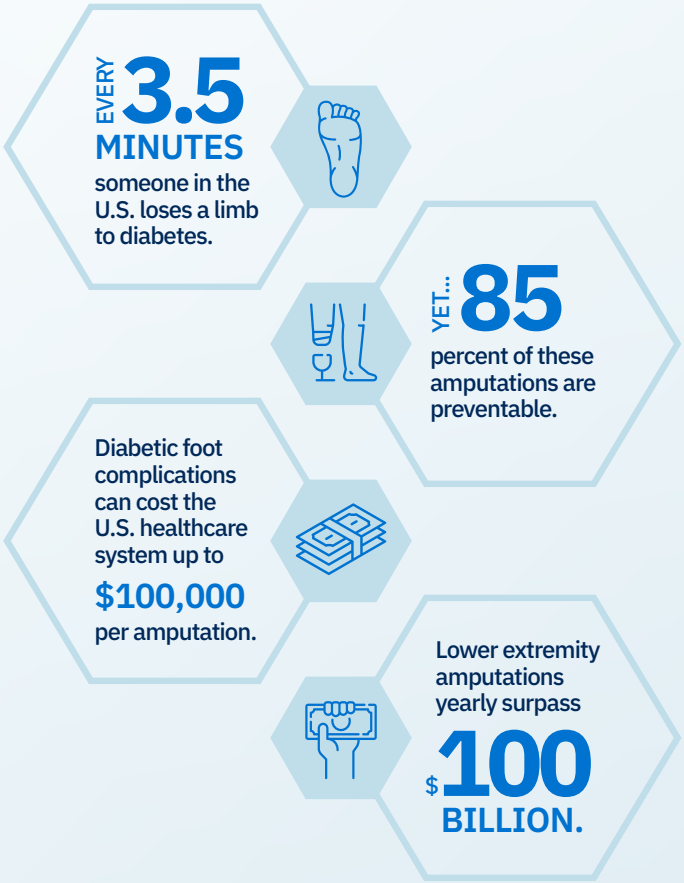
A common approach used by insurers' medical economics teams is to apply a difference-in-difference framework between a Study Group and a Matched Control Group. The theory is that the Study Group should see an improved trend from a Matched Control Group if the intervention has worked as intended. For this approach to work, the Control Group needs to be otherwise identical to the Study Group. Any differences create noise in the conclusion. This approach is problematic when an event needs to occur in order to be attributed to the Study Group. We will focus on one example of an intervention for a specific disease criteria, DFUs, to illustrate a common flaw in this approach and present an alternative approach to measurement that overcomes this critical issue.

DFU Challenges: A Deep Dive

Every 3.5 minutes, someone in the U.S. loses a limb due to diabetes, yet 85% of these amputations are preventable.[3] Diabetic foot complications are the leading cause of amputations in America, impacting quality of life and costing the healthcare system up to $100,000 per amputation.[4,5,6] Complications add to the burden, with lower extremity amputations surpassing $100 billion yearly.[7]

In a typical Medicare Advantage (MA) plan, about 1% of members in a given year will experience a DFU but these 1% of members drive around 3.5% of total costs to the MA plan and experience 4.5 times as many admissions and 3.3 times as many ER visits as the rest of the population.[8]

Temperature monitoring programs, utilizing devices like the SmartMat™ combined with integrated clinical support services, can help identify foot ulcers early, allowing for intervention and prevention of amputations. A historically rooted and evidence-based solution to prevention of diabetes-related lower extremity complications is in-home foot temperature monitoring. The causal pathway to lower extremity amputation among people with diabetes will commonly begin as inflammation, which then leads to ulceration, infection, hospitalization, and, ultimately, amputation.



Making a Compelling Pitch to Insurers

While identifying foot ulcers can be life-saving, a technology that does this can only have an impact when it's effectively delivered to those who need it most.[9] Achieving success involves more than just having the right technology — it also requires identifying the right patients, securing insurance approval for coverage, and encouraging patient use of the device. VBC can accelerate adoption of such technology, but insurance companies need to believe the economics will work prior to deploying the solution. Real-world clinical and economic evidence from other studies is helpful, but ultimately an insurer wants to know what the opportunity looks like for their population. A provider that can get in front of the right patients, measure their results accurately, and assess an insurer's specific opportunity is equipped to take some level of direct financial risk on their target population.

We have found the following approaches help with securing insurer buy-in:

- **Quantify the size of the issue from an insurance point of view**
- **Identify the right patients for the program**
- **Enable risk-based contracting options by pricing the right population accurately**

Finding the Right Patients

Around 40% of members with a DFU in the current year will have a repeat DFU in the following year.[9] This recurrence creates a natural attribution approach; however, it is even more valuable to prevent an initial DFU from forming in the first place. For this particular program, we either attribute members based on a history of DFU or deploy a machine learning model that predicts future DFUs. With the predictive model in place, we can get in front of a majority of DFUs *before* they occur by only focusing on members with the highest risk of DFU (typically <2% of the population). By leveraging this predictive model, we can anticipate and mitigate over 60% of DFUs in the following year, providing a quantifiable impact on prevention efforts and overall patient outcomes.

Challenges to Accurate Measurement

Measuring outcomes from program interventions requires consideration of several key elements:

- **Who exactly is in the Study Group? This requires specific diagnosis code definitions.**
- **When exactly are their results included? This requires specific timing rules related to incurred and paid dates.**
- **What specifically is the outcome variable? We frequently look at total cost of care and MLRs but may also include utilization and quality measures.**
- **Who are we comparing results to, and how are those results normalized to predict the actual experience of the Study Group without intervention?**

In this particular case, a large challenge with accurate measurement is that costs spike the months around an active DFU and then regress downwards for several months until they eventually plateau or a patient re-ulcerates, leading to another cost spike. (DFU identification for these statistics relies on a claims-based approach using DFU codes.) As such, it is difficult to do a typical pre-post analysis or a matched control study as timing relative to DFU is a key determinant of how much a member would cost without intervention. A simple pre-post analysis would incorrectly either show significant cost increase if measuring costs before DFU to costs after DFU or significant cost decreases if measuring costs after member identification for program eligibility (when we are closer to the DFU event) to costs after identification (when we are further away from the initial DFU event). Both approaches are flawed because they have not correctly predicted what costs would naturally be without intervention.

To illustrate this point, Tables 1 and 2 show cost trajectories by month relative to initial DFU occurrence for both commercial and Medicare national populations. Looking at the Medicare cost averages around DFU (Table 2), flawed study design #1 might show a pre-cost of around $2,200 per member per month (PMPM) with a post-cost of $3,600 PMPM (assuming the calculation compares results between the year before DFU to the year after DFU). Thus, without any intervention, we would incorrectly conclude losses of around $1,400 PMPM. If, instead, we set the index point at Month 3, assuming members are not identified for intervention until then due to claims and operational lag, we would conclude pre-costs of $3,800 and post-costs of around $2,600, which would incorrectly show savings of $1,200 PMPM.

Table 1: Utilization and Cost Trajectory Around DFU Occurrence — Commercial[8]

Time Period	Med Allowed PMPM	Admits/1,000/yr	ED/1,000/yr	Amputations/1,000/yr
Month-12 to -7	$1,437	236	734	1
Month -6 to -4	$1,828	251	786	1
Month -3	$2,624	295	757	0
Month -2	$3,088	381	912	11
Month -1	$4,036	568	1,306	14
Month 0 (Month of DFU observation)	$10,121	2,542	4,374	517
Month 1	$4,778	749	1,281	251
Month 2	$4,312	649	1,201	174
Month 3	$3,322	445	1,029	99
Month 4-6	$2,879	435	1,000	102
Month 7-12	$2,461	384	859	53
Month 13-18	$2,268	309	810	48
Month 19-24	$1,933	363	912	37

Both approaches result in a flawed conclusion. A common medical economics approach is to layer on propensity matching (matching members from the intervention to members without the intervention based on medical diagnoses and demographics) and/or conduct a difference-in-difference calculation (comparing how costs change over time between members in the intervention and a control group). While both approaches improve measurement accuracy, if they do not perfectly account for the timing of DFU between Study and Control, they will still be subject to the material incorrect conclusions we illustrate above. In addition, the intervention itself, utilizing a SmartMat Program and clinical support services to help identify DFUs early, can influence the natural timing of DFU detection and documentation in claims, which creates further distortion in a matched control study.

Table 2: Utilization and Cost Trajectory Around DFU Occurrence — Medicare[8]

Time Period	Med Allowed PMPM	Admits/1,000/yr	ED/1,000/yr	Amputations/1,000/yr
Month-12 to -7	$1,681	579	1,062	2
Month -6 to -4	$2,124	750	1,202	5
Month -3	$2,645	971	1,409	5
Month -2	$2,941	1,073	1,522	12
Month -1	$3,746	1,455	2,024	28
Month 0 (Month of DFU observation)	$7,034	3,344	3,871	424
Month 1	$5,808	2,010	2,109	249
Month 2	$4,457	1,443	1,728	154
Month 3	$3,800	1,269	1,615	121
Month 4-6	$3,109	1,063	1,431	74
Month 7-12	$2,738	933	1,309	49
Month 13-18	$2,564	829	1,211	35
Month 19-24	$2,574	838	1,202	36

An Approach to Accurate Measurement

We are able to account for this timing issue as well as all the key elements outlined above to establish a target price for a VBC arrangement and produce an accurate conclusion of outcomes resulting from the deployment of an early DFU detection program with temperature monitoring technology. This method works well for most types of clinical programs across lines of business (Medicare, Commercial, and Medicaid). The methodology requires the following components:

1. Complete and accurate claims and eligibility data (and revenue data if establishing a MLR target) spanning several years of history, including members who have terminated coverage during the historic period (members who have terminated coverage tend to have greater expense and higher MLRs than members maintaining coverage due to the fact that terminations are correlated with death).

2. Replicate attribution and exclusion rules on the historic data as if the program was live in the historic period. This means simulating all processes around attribution, exclusions, and carve outs historically as they would have occurred. For example, if attribution is done quarterly with one month of payment lag, then historic attribution needs to be done identically. If exclusions are retroactive to the first day of the month of the service date associated with the exclusion, then exclusions need to be applied retroactively as well as of the first of the month. If settlement/ROI calculation will be done with 3 months of payment run out, then the historic baseline needs to reflect this limitation as well. Any deviation in production from what would have actually happened historically creates bias and leads to inaccurate conclusions.

3. Track attributed member experience following their simulated attribution date for the outcome variables that will be at risk. This typically includes financial liability, duration of coverage (member months), and revenue if proposing an MLR deal. This could also include key utilization metrics like admissions, ER visits, and amputations.

4. Observe the simulated attributed population metrics over time. Typically, the first year will have very different experience than ongoing years because an excess bolus of members are attributed in the first attribution cycle (subsequent attribution runs contain members who, by rule, have not previously been identified), but this pattern depends on the exact attribution requirements.

Returning to our example of DFU, output from this baseline-setting exercise might yield something like the following:

Table 3: Simulated Baseline Results for Target Price Setting

Year	1	2	3
Members Identified and Surviving into Year	500	700	800
Attributed Member Months During Year	3,200	5,200	6,400
Medical PMPM After Attribution	$3,350	$3,100	$3,080
MLR After Attribution	185%	150%	155%
IP Visits After Attribution per 1,000 Members per Year	1,200	1,000	1,050
Amputations After Attribution per 1,000 Members per Year	100	80	75

From these results, we can establish a PMPM, MLR, or utilization target. It is critically important to also factor in any changes in environment or population and risk mix that would affect these prices in the next set of years. For example, for contracts in 2025 or 2026 that are based on historic data from 2022-2023, an MLR target should be repriced to account for changes in the CMS-HCC model from v24 to v28 and impacts from the Inflation Reduction Act on the Part D MLRs if Part D is in scope. If there are no changes, or these have already been factored in appropriately, it would be reasonable in this case to set an MLR target as the average of Years 2 and 3, 152.5% in this example. Results in the next years following identical attribution cycles can then be compared against this target price to determine if the intervention has indeed reduced the MLR (or other outcomes metrics) of the target population. MLR naturally includes changes in risk and trends, but these elements need to be adjusted when measuring other outcomes metrics. Conducting measurement on the entire attributed population, rather than just the engaged population, also eliminates any selection biases between members choosing to engage, or not engage, in the program.

Key Takeaways

While VBC has the potential to advance the objectives of the Triple Aim, VBC contracts need to be measured accurately to achieve desired outcomes. For disease-specific risks, like DFUs, standard medical-economic approaches may not appropriately quantify financial and utilization outcomes associated with programs designed to prevent consequences associated with these diseases.

We have illustrated why it can be challenging to measure financial outcomes when attribution is based on a particular event, such as a DFU. We have also presented a general framework to approach reasonable target price setting for VBC arrangements. We have only scratched the surface of all the considerations that should be made in a VBC contract methodology, but we have outlined major areas of consideration with examples from a DFU prevention program.

References

1. https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-and-losses-and-assignment-methodology-specifications.pdf-2
2. https://www.cms.gov/priorities/innovation/innovation-models/aco-reach
3. American Diabetes Association
4. Brownrigg, et al. Euro J Vasc Endovasc Surg. 2013
5. Hicks, et al. Ann Vasc Surg. 2016
6. California Healthline
7. Armstrong et al. J Foot Ankle Res. 2020
8. National data presented here comes from Meritave's Marketscan data. The interpretation of this data is that of the authors and is not a representation from Meritave.
9. Armstrong, et al, N Eng J Med. 2017

podimetrics

PODI-0219 Rev A