

ADHERENCE & ACCESS

Rethinking engagement with remote foot temperature monitoring (RTM) programs

INSIGHTS FOR PAYORS & HEALTH SYSTEMS



Despite an urgent need for preventive solutions like remote foot temperature monitoring (RTM), many patients still face limited coverage for technologies that can reduce catastrophic complications of type 2 diabetes (T2D) — including diabetic foot ulcers (DFUs), lower extremity amputation (LEA), and elevated mortality risk.^{1,2} In this white paper we'll delve into the connection between adherence and access, and how rethinking it can help enhance patients' outcomes.

Explore	the unique adherence challenges facing people with T2D and its complex complications.
Examine	how questions and concerns about adherence can shape these patients' care.
Discover	how the Podimetrics SmartMat™ Program helps solve key adherence challenges by design.





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"Will patients really use it?"

Today's payors & "payviders" have to balance countless complex factors in their coverage decisions. But all too often, questions about adherence tip the scale toward access restrictions.

Perhaps more than ever, payors and health systems have good reason to ask those questions. Adherence is both vital to clinical outcomes and a well-known challenge.³ The healthcare landscape is no stranger to products that excel in the lab or clinic, but fail to keep patients engaged in real-world use.

One technology that's *not* on that list, however: **RTM**.

Solutions like the SmartMat Program have helped deliver proven benefits in both clinical and real-world settings, and yet this valuable preventive approach often faces the same skepticism many effective remote modalities encounter: Will it *actually* be used as prescribed? Will patients stay engaged without a provider's oversight?

To rethink this question, read on...

In this white paper, we'll explore why the answer is definitely *yes*, and often despite the many and persistent adherence challenges faced by people with DFU. Innovative solutions like RTM can play a vital role in preventing the enormous personal and financial cost of this condition — but only if patients can consistently access these proven preventive technologies.

Here we'll examine both the scale and acuity of that challenge, what it means to achieve meaningful adherence to an RTM program, and how those programs can be purposely designed to support real-world adherence success.

1

DFU & LEA: A crisis compounded by persistent access barriers

Together, DFU and LEA have become a clinical, social, and financial crisis for the U.S. healthcare system.⁴ And yet, many patients still face limited coverage for effective new preventive approaches — even clinically validated ones like RTM — due to doubts about adherence. Let's look closer at the growing impact of this catastrophic cascade, and how effectively it can be addressed with access to solutions like the SmartMat Program.

Every 3.5 minutes, someone in the U.S. **loses a limb due to complications of T2D**.⁵

The human and systemic costs are immense, especially when the vast majority of these events are preventable. It's a crisis we can solve — but only with access to the right preventive solutions.

Diabetic foot complications take a staggering toll on patients and health systems alike. With T2D now the leading cause of non-traumatic amputations in the U.S., there's a clear and critical need for innovations that can help effectively contain the growing costs of DFU and LEA.

BALLOONING COSTS



driver of excess medical costs associated with T2D: diabetic foot care.⁴

>\$**100**B

is the current total cost of lower extremity complications.^{1,4}

>\$**100**к

is now the cost of a single diabetes-related LEA.⁶

PROFOUND IMPACT

50%

of patients who experience diabetes-related LEA may be dead in just 2 years.⁷ 150,000

people with T2D undergo an LEA every year.⁵

85%

of diabetes-related LEAs are preventable.⁸



Fortunately, an effective solution is already available.

But it's one that has yet to gain broad, consistent traction with payors and health systems — despite demonstrated benefits in both clinical and real-world settings.

In both the clinic and the real world, RTM has shown that it's an effective way to both prevent DFU and LEA and reduce the significant costs associated with this severe, life-changing complications.^{9,10,11,12} And yet, across health plans and systems, adoption and implementation of this proven solution remains inconsistent at best.

That's a challenge that needs to be addressed more urgently than ever.

The SmartMat[™] Program: A proven approach to RTM

Purpose-built to prevent DFUs and LEAs, the SmartMat RTM Program is an innovative approach that meets at-risk patients where they are to create better outcomes.

More than simply a smart RTM device, this program combines technology, monitoring, and personalized support to help deliver a difference for patients, providers, and payors alike — all with one 20-second scan per day. Clinical evaluations and real-world deployments have both shown that the SmartMat Program has a significant positive impact, even in traditionally non-adherent populations like Veterans and Medicaid groups.^{10,11,12,13}

Holistic **components**

The SmartMat Program is built to support patient affinity and adherence in diabetic foot care.



Clinically validated RTM device

Easy to set up and use, and clinically proven to detect the earliest signs of inflammation.

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✓=	

Seamless provider collaboration

Personalized reports and updates to help providers tailor interventions to each patient.



Personalized patient support options

Proactive monitoring and regular engagement calls delivered by a dedicated team of nurse care management specialists.

Powerful outcomes

The SmartMat Program helps make a clinical and financial impact where it matters most with these documented results.¹⁰



With consistent access for at-risk patients, the SmartMat RTM Program is a solution that can help dramatically advance preventive care for DFU. The clinical and financial evidence is there. But to unlock the full potential of approaches like the SmartMat Program, we need to fully understand the factors that shape adherence in the T2D patient population — and change the conversation about how that achievement is measured.

2

Adherence & T2D: Unique and acute challenges across the care journey

Adherence can often be an especially complex process to navigate for patients with T2D. As with many "traditionally non-adherent" populations, doubts about engagement often lead to limited coverage for effective new solutions — even ones that may be purposefully designed to lower the unique barriers these patients face.

To overcome that challenge, we need a better understanding of why adherence shortfalls occur, and how they can be addressed before they limit patients' access to effective care.

For patients with T2D, perceived adherence risks can create one more barrier to consistent care.

To meet the challenge of DFU and LEA, we need a better way to balance reasonable reservations with the realities of diabetic foot care. This starts with a better understanding of what really shapes adherence for people with T2D.

There's no doubt: Non-adherence is a pervasive challenge that payors and health systems have good reason to focus on.³ For patients with T2D, poor adherence rates can lead to suboptimal therapeutic outcomes, greater likelihood of ER visits and hospitalization, and higher readmission rates — all of which can have a serious negative impact on both patients' quality of life and a health system's bottom line.^{14,10}

But while these risks are real, they often overshadow real opportunities to advance patients' care — especially when it comes to complex care pathways like T2D. Many of these patients have crisis-level unmet needs when it comes to effective diabetic foot care. Yet all too often, coverage decisions default to doubt when weighing clinical benefits and potential adherence risks.

To put those concerns in context, let's take a closer look at the many reasons why patients with T2D often struggle with adherence — especially when it comes to foot care.

Daunting barriers: Adherence & T2D

Patients with T2D must juggle an overwhelming range of logistic, financial, and personal demands at every stage of their care — from overlapping comorbidities, to polypharmacy, to care system fragmentation, and far beyond.¹⁵ These are just some of the formidable barriers that often stand between these patients and consistent adherence.

PATIENT FACTORS

Health literacy

Faced with a bewildering array of care considerations to manage, it's no surprise that patients with T2D often report that they struggle to fully understand their foot-related care.¹⁶ With a limited grasp of how and why to manage their foot health, many patients experience adherence shortfalls that could be addressed with more comprehensive educational support.

Diabetes distress

The sheer psychological load of managing diabetes can become debilitating and disempowering, lowering patients' motivation to stay adherent. Patients experiencing these feelings often find themselves caught in a vicious feedback loop if they abandon adherence: being labeled as "difficult," "noncompliant," or otherwise uninterested in getting better, further reinforcing their distress.¹⁷

PROVIDER FACTORS

Provider shortages

The U.S. healthcare system is acutely understaffed, and diabetes care providers are no exception. When providers don't have the resources to maintain regular contact with patients, it can result in substantial drops in patient adherence. This can be particularly acute when already limited resources are further depleted in medically underserved areas (MUAs).¹⁸

Siloed care

Providers themselves cite challenges with interprofessional communication as a major factor impacting patients' adherence to diabetic foot care.¹⁶ This can be especially difficult in multidisciplinary treatment pathways like T2D, where patients and their medical information are frequently exchanged across multiple different disciplines, practices, and EHRs.

SYSTEMIC FACTORS

Direct-to-patient costs

To stay consistent with a prescribed treatment, patients first need to be able to afford their prescription. When a patient has difficulty affording out-of-pocket costs, it can disrupt their supply and lead directly to reduced adherence.¹⁹

Decentralized care

In the notoriously fragmented U.S. healthcare system, simply acquiring prescribed treatments and supportive resources can be exorbitantly difficult for many patients. When their care spans different clinics, specialists, pharmacies, DME vendors, and more, patients often find it difficult to consistently coordinate all their sources of care.²⁰

But these aren't the only headwinds holding back preventive care for DFU

Another persistent challenge also stands in the way of consistent coverage for solutions like RTM: defining the level of adherence new approaches need to achieve to win consistent coverage.

To build the confidence they need to cover new approaches, payors and health systems naturally need to see compelling evidence that a product or treatment can facilitate good adherence. But the benchmark for "good"? That's a standard that can be confoundingly difficult to pin down.



Social determinants of health (SDoH):

An especially complex array of social factors converge in the care of patients with T2D individuals who are often heavily overrepresented in racial and socioeconomic communities that face profound structural inequities. Race and ethnicity, disability status, financial security, food security, and many other SDoH can all have an impact on patients' ability to maintain the continuity of their own care.²¹







3

Pick your target(s): Navigating heterogeneous adherence benchmarks

Variability is one of the few consistent features of today's adherence evidence. Established, broadly covered care modalities are often supported by widely divergent adherence data, clouding the standards that potential new plan additions need to meet to secure coverage. Let's take a closer look at what that can mean for patients with DFU and their preventive care.

So many accessible treatments, **so many adherence standards**.

When it comes to coverage determinations, this often seems to be the challenge awaiting solutions like RTM. So what's the best way forward when current standards offer cloudy guidance?

Adherence is just one of many different considerations that factor into coverage decisions, but it's a particularly difficult one to evaluate objectively. Patients often face multidimensional adherence barriers, as they certainly do with DFU prevention. At the same time, payors and health systems face their own significant challenge: simply defining a threshold for confidence-building adherence.

Having a clear standard is critical for any objective evaluation of adherence, but it remains elusive for many new therapies and products. Existing therapeutic and supportive T2D standards of care measure patient persistence in remarkably diverse ways, and many widely accessible modalities deliver marginal results by their own varying standards — adding further confusion to coverage determinations.

No clear standard among standards of care



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Each of these examples is a generally accessible therapy or resource, with broad if varying coverage across U.S. health systems and plans. And yet each one demonstrates the same challenge: there's no clear, singular answer to what "good" adherence means for patients with T2D.

To find a place among incumbent care options, new therapies and products need to stake out what "good" should look like for their own modality — and *then* demonstrate that they consistently meet it.

ONE THING IS CLEAR:

We need more than another standard for RTM

To ensure patients have consistent access to RTM, we can't settle for just another heterogeneous benchmark for adherence performance. Instead, we need a consistent, objective way to evaluate all the critical dimensions of adherence to RTM: Clear goals for patients, purposeful support for their efforts, and evidence that demonstrates successful, sustained adherence.

And with the SmartMat Program, it all comes together.



Defining success: How the SmartMat Program helps set a patient-centric standard

With our leading-edge RTM program, we set out to create more than an effective remote monitoring solution. Our true goal: To create a comprehensive, holistic care model that supports consistent adherence by design. At every step, we've kept our focus on one essential goal: defining a meaningful standard that supports our exceptional, documented clinical outcomes. Let's look at how the evidence points to an adherence threshold that's both consistent and demonstrably achievable.

The evidence is clear: For RTM adherence, the SmartMat Program shows what exceptional should look like.

Looking closer at the data, we can see what payors and health systems are looking for: consistent, sustained utilization that supports exceptional outcomes.

From the launch of this innovative program, we've stayed focused on the goals that matter most: helping to protect the health of people with DFUs and stopping the skyrocketing costs of diabetic foot complications. To get there, we've worked closely in conjunction with payors and providers to create a model that keeps patients engaged, committed, and supported — with clear benchmarks for that success. As we built that collaboration, we identified three key factors that are essential to assessing an RTM program's true adherence performance. Each one is individually valuable. But together, they point to a solution that can sustainably advance patient care and secure payor and health system's confidence.



Demonstrated attainability In the end, it's the evidence that matters. An effective RTM program needs to show that it not only kept patients engaged, but that that engagement correlated with better outcomes.

Durable attainability It's not enough for patients to start strong and then lose track of their treatment. A successful RTM program needs to show that it can keep patients consistently engaged long-term.

Real-world attainability Busy, care-burdened patients will inevitably miss or forget self-care steps. An approach like the SmartMat Program needs to deliver benefits at a level of adherence that's realistic in day-to-day use.



By each of these benchmarks, **the SmartMat Program excels**.

The answer is: *Yes,* patients really use it.

Once patients have been enrolled in the SmartMat Program, they actively and consistently engage with it. Scan data show that more than 4 out of 5 users step on that mat as directed multiple times a week.

DEMONSTRATED ATTAINABILITY



of patients enrolled in the Podimetrics SmartMat Program scanned at least 1-3 days a week (avg)¹²

Lasting adherence: Most patients are still regularly scanning at 12 months.

Our users build a stable, consistent routine around their monitoring scans. At the one-year mark, 7 out of 10 SmartMat Program patients still actively use their monitoring device as part of their self-care regimen.

DURABLE ATTAINABILITY

70%

of patients in the Podimetrics SmartMat Program remained engaged at the one-year mark.¹¹

Practical persistence: Users see the benefits with several weekly scans.

While the SmartMat Program is indicated for everyday use, patients concurrently managing multiple complex health demands may still have difficulty completing a scan each and every day. Even 20 seconds a day can get lost in a busy schedule full of other self-care responsibilities.

We can see that across the SmartMat Program's adherence results: Perfect performance may be rare, but patients still achieve excellent outcomes at a realistic level of adherence. Across studies and patient groups, the SmartMat Program delivers significant preventive outcomes and cost-saving benefits at a consistent and achievable adherence threshold of 1-3 scans per week.^{9,10,11,12,13}

REAL-WORLD ATTAINABILITY



1–3 scans/week

typical number of scans at which patients achieve the standout clinical results demonstrated by the SmartMat Program.^{12,13}

How the SmartMat Program measures up to other remote monitoring solutions

Data for many modern remote monitoring programs is still nascent. Yet looking at this evolving utilization data, it's clear that the SmartMat Program stands apart among similarly structured technology+support care offerings.

Of course, direct comparisons to other care modalities are always rough, given the variability in patient types, severity of their health condition, and adherence benchmarks applied. However, raw figures demonstrate that the SmartMat RTM Program users attain clear, achievable, effective adherence targets more often than many patients using other increasingly popular remote care solutions.

SmartMat RTM Program^{11,13}

Adherence standard:

1-3 scans/week, % of patients actively using the monitoring device at the 1-year mark Adherence rate: 70-80% completed 1-3 scans/week, 70% still actively scanning at one-year mark Remote monitoring of glucose metrics & self-management behavior²⁸

Adherence standard:

One engagement with digital platform per week; regular weekly medication logging Adherence rate:29% engagement rate,44% logging completed

Real-time continuous glucose monitoring (CGM)^{16*}

Adherence standard: Proportion of days covered (PDC)≥0.8 Adherence rate: 56.8% in patients on intensive insulin therapy (IIT) for T2D

Remote monitoring of oral antidiabetic drugs (OAD) adherence²⁷

Adherence standard: OADs on hand at least 80% of covered days Adherence rate: 70%

Follow the coverage & access trends

Interestingly, the SmartMat Program adherence rates also compare favorably with the raw, real-world adherence rates for real-time CGM for patients with T2D on intensive insulin therapy (IIT).²⁶ Yet even with their comparatively lower adherence rates, CGM devices have recently begun to gain more traction with major payors.²⁹ RTM should be next.

Adherence by design: How the SmartMat Program was built for effective engagement

The SmartMat Program's standout adherence results are no accident. We designed it from the ground up to lower barriers and mitigate the substantial challenges patients with T2D face in managing their foot care and limb health.

Achievable, sustainable, proven: **RTM is an adherence success**

From its patient-centric design to its proven real-world results, the SmartMat Program shows how RTM can be managed in a way that keeps patient engagement at a consistent, effective, impactful level.

With evidence like this, it's time to reassess the doubts that continue to restrict access to this powerful technology. After all, continuing to spend millions on diabetic foot complications is not a solution — but the SmartMat Program is.



PURPOSEFUL PROGRAM DESIGN

Ease of use

The simple setup, intuitive functionality, and rapid scans make it easy for patients to perform daily foot scans, even if they have mobility challenges or compromised dexterity.



straight to the patient's door and can be used for up to one year without needing to be replaced.



of their foot health.



One-to-many model

The SmartMat Program's Patient Support team manages multiple patients for a single physician, breaking resource bottlenecks and expanding patients' access to timely preventive care.

What's next for **RTM**

For all of us at Podimetrics, we hope this discussion helps inspire fresh thinking on the promise of RTM solutions, and how we can all help patients achieve consistent adherence.

From the launch of the SmartMat Program, we've stayed focused on the goals that matter most to patient enrollees, the providers who guide their care, and the payors and health systems that trust us to support their covered lives. But while we're excited by the impact our program has achieved, we know there's much more still to do.

The crisis of DFU/LEA is one that will only be solved by continual innovation, collaboration, and exploration — challenging assumptions and perceptions that may be holding back patients' care along the way. Adherence will always be at the forefront of all those efforts, keeping our focus on what patients really need to unlock the full impact of their care.

And that's right where that focus will always belong.



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