Remote Patient Monitoring: Prevention of DFUs

Put this technology into practice as an adjunct to shoe fitting.

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Last year, *PM* published an article describing remoting patient monitoring (RPM), a new Medicare initiative to promote preventative care of chronic conditions (https://podiatrym.com/pdf/2020/10/White-1020web.pdf). The piece described qualifications for coverage, parameters that could be measured, and devices that can be used. It also detailed how Medicare allows physicians to bill approximately $125 per patient per month. Two companies have emerged as leaders in podiatric RPM and both focus on preventing diabetic foot ulceration by monitoring foot temperature. A sustained elevation of two degrees Celsius can be indicative of impending neuropathic ulceration and so if detected, provides an opportunity for intervention. Alerts can direct patients to take pressure off the bottoms of their feet, inspect inside their shoes for foreign objects, check for areas of redness or blistering, and make an appointment to see their podiatrist.

Last year, only a handful of podiatry practices were utilizing RPM. While far from mainstream, many have now started; some have tried and stopped, some are just getting going, and others are using RPM to provide care to scores of patients. Without appropriate follow-up care, 50% of ulcerated patients who heal reulcerate within a year; over 50% die within five years.[1] Next year, I plan to write a follow-up article to report on patients who have healed foot ulcerations and subsequently been provided therapeutic shoes, inserts, and enrolled in RPM to protect against subsequent ulceration. It's exciting to speculate about the potential of this way to improve patient quality of life and reduce Medicare costs.

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Review of Remote Patient Monitoring and How Telehealth Use Was Accelerated by Covid

Remote patient monitoring is the use of digital technologies to collect physiological health data from patients in one location and electronically transmit that information securely to healthcare providers in a different location for assessment and recommendations. RPM services include establishing, implementing, revising, and monitoring a specific patient treatment plan related to a chronic condition. RPM may be used to promote patient self-care, monitor patients' key measures, and allow providers and patients easy access to information about patient health issues. Remote patient monitoring aims to allow more of physician office time to be used for visits that require more complex intervention.

The Covid pandemic accelerated many practices and patients adopting telehealth initiatives. To improve access to care, Medicare accepted a broader array of communication modalities by providing physician reimbursement comparable to in-person visits. The pandemic also prompted many older people to become more familiar with and comfortable doing things on-line. These factors, along with rapid development and reduction in the cost of Internet-connected monitoring devices, have resulted in a large year-over-year increase in adoption of remote patient monitoring.

Employing RPM means first deciding what to measure. According to Medicare guidelines, monitoring entails "physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate)". The parameter must be within the practitioner's

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scope of practice. There has not been more specific guidance beyond the provided examples as to what other conditions Medicare considers acceptable. By 2050, half of all seniors are predicted to be obese. These 42 million people will either have diabetes or, by definition, be pre-diabetic. At $43 billion per year, the cost of diabetic limb complications is more expensive than any form of cancer.[2] 5% of patients with a DFU required a major amputation in one year.[3] Diabetic foot ulceration is associated with a 5% mortality in the first 12 months.[4] Remote monitoring technology can prevent ulceration, reduce healing time, and keep healed ulcers "in remission". RPM offers the promise of fundamentally changing the current approach to diabetic foot care by stratifying patient care according to their risk level, in real time, and allowing physicians to focus on providing in-person care when most warranted.

TABLE 1

Annual RPM Revenue per Patient

	1st Month	Months 2-12	Annual Total
Setup (99453)	$19		$19
Equipment + Data Transmission (99454)	$64	$64	$768
Viewing Data, Communicating with Patient—Initial 20 Minutes (99457)	$52	$52	$624
Viewing Data, Communicating with Patient—Additional 20 Minutes (99458)	$42	$42	$252*
	$177	**$158**	**$1,663****
Annual revenue opportunity of per year per patient, or higher**			

*Assumes spending additional 20 minutes for 50% of monthly communication.
**Does not include cost of equipment or software or monitoring service.

Therapeutic footwear, provided it includes plantar pressure relief, and is consistently worn by the patient, is effective in preventing relapses in diabetic patients with previous ulceration. One study demonstrated that after one year, foot ulcer relapses were significantly lower (27.7 vs. 58.3%).[5] Despite the effectiveness of shoes and inserts at preventing DFUs, patient adoption has been limited. Some of the reasons that patients at risk for ulceration fail to wear prescribed therapeutic shoes are unintentional and can include:

- Failure to appreciate the importance of off-weighting.
- Failure to appreciate the significance of small periods of weight-bearing.

Combining RPM with shoe fitting offers podiatrists the opportunity to more than triple the revenue earned, per patient, per year.

- Failure to appreciate the number of steps taken.[6]

Monthly communication, as part of remote patient monitoring, offers the opportunity for instructions to better resonate. RPM provides communication in real time about conditions contributing to increased risk that patients otherwise would not be aware of. One of the reasons for podiatrists not fitting their diabetic patients with shoes is the perception that Medicare does not offer adequate reimbursement. Combining RPM with shoe fitting offers podiatrists the opportunity to more than triple the revenue earned, per patient, per year.

The companies that are working most closely with podiatrists to adopt remote patient monitoring are focused on preventing diabetic foot ulceration by monitoring foot pressure and / or temperature as a qualifying parameter. Orpyx Medical Technologies, https://www.orpyx.com/for-providers, provides plantar pressure, temperature, hours of wear and step count monitoring via custom diabetic insoles while Siren, https://www.siren.care/for-providers, provides socks that integrate temperature monitoring technology. Both monitor steps taken, and whether the device is being worn. Both offer mechanisms for communicating directly with patients on an as-needed basis, provide on-going reporting to the physician and monthly communication with patients.

What to Use and When—Indications for Podiatric RPM

Practices using either Siren or Orpyx will have the greatest success when either program is prescribed for patients with a history of ulceration. These patients are most aware of the difficulty and time to heal wounds and should be most motivated to do what it takes to prevent recurrence and, with it, the associated possibility of amputation. Orpyx recommends that its custom insoles be used for patients with

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mild to moderate foot deformities or those without foot deformities at risk of ulceration. Significant foot deformities requiring deep accommodation or when there is the need for a partial foot filler, will be best accommodated by custom made insoles that do not employ Orpyx embedded sensors. Remote patient monitoring can still be provided for these patients using Siren sensor embedded socks. Patients at risk for ulceration because of decreased circulation and/or loss of protective sensation but who do not have any structural deformities and so do not need custom insoles, might be best accommodated with shoes, pre-fabricated insoles, and Siren socks.

Coding and Billing for RPM

Billing for remote patient monitoring is akin to how it works for cell phones and cable television. Physicians are reimbursed for the cost of providing the patient the product, and there is ongoing monthly reimbursement to cover the cost of monitoring the patient and providing real-time communication.

CPT 99454 offers reimbursement for providing the patient with an RPM device for a 30-day period. 99454 can be billed each 30 days.

CPT 99453 offers reimbursement for the work associated with onboarding a new patient onto an RPM service, setting up the equipment, and educating the patient on using the equipment. In January 2020, Medicare changed its rules to allow RPM services to be delivered by auxiliary personnel who can be in a different location from the supervising physician. Remote patient monitoring can be done by representatives from NavCare (https://navcare.com/blog/remote-patient-monitoring-for-diabetic-peripheral-neuropathy-can-reduce-diabetic-foot-users-and-amputations/), Orpyx's partner company, and by in-house technicians when using Siren socks.

The 2021 national Medicare payment for these services is approximately $18.77. Requirements for RPM include:

- Patient must opt-in for the service
- Patient cannot be charged for the device.
- Device must meet the FDA's

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definition of medical device and capture physiological data.

- Physician must order the device.
- Documentation must include:

– Nature and severity of the patient's condition

– Detailed history of the condition

– Medical necessity and clear rationale for monitoring

– Goals to be achieved by RPM

CPT 99454 offers reimbursement for providing the patient with an RPM device for a 30-day period. 99454 can be billed each 30 days. The 2021 average national Medicare payment is approximately $64.15.

- Device must be supplied for at least 16 days during the billing period.
- The service must be ordered by a physician or other qualified healthcare professional.
- Data must be wirelessly synced where it can be evaluated.
- RPM may be used with either CPT 99091 or 99457.
- There is no minimum number of measurements that must be collected each day.

CPT code 99457 is for Interpretation and Management: "Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month, first 20 minutes."

CMS will reimburse for staff time that contributes toward monitoring and interactive communication which includes phone, text, and email. The 2021 average national Medicare payment for these services is $51.61.

- Report once each calendar month.
- Do not report in conjunction with CPT 99091.
- Do not count any time on a day when the physician reports an evaluation/management service.
- May be billed as an "incident to" service.
- Requires live, but does not have to be in-person voice communication.

Services billed as "incident to" must be an integral, though incidental, part of the billing practitioner's service in the course of the patient's diagnosis or treatment. This means the practitioner submitting the bill must furnish an initial service (e.g., an E/M visit) to which the subsequent RPM services are integral and incidental, establishing the patient relationship prior to furnishing RPM.

Both Siren and Orpyx systems provide the podiatrist with charting to support time spent reviewing data and communicating with patients to support the billing.

CPT 99458 allows for the physician or clinical staff, under general supervision, to provide when the complexity of the patient's condition warrants it, additional interactive communication beyond the initial 20 minutes. The 2021 average national Medicare payment for these services is $42.22.

How to Get Started Adding RPM to Diabetic Shoe Fitting

The Task Force of the Foot Care Interest Group of the American Diabetes Association recommends that all patients with diabetes be given an ulcerative risk assessment at least annually. This exam provides the opportunity to document the medical necessity to qualify for Medicare coverage for shoes and inserts. Findings that support prescribing shoes/inserts might also suggest prescribing remote patient monitoring. Both Orpyx and Siren perform onboarding, daily patient monitoring, and monthly communication such that once patients are prescribed RPM, the rest of the process is truly "turn-key".

Practices do best at fitting shoes when there is a dedicated, trained, motivated person in the practice to whom the physician can easily refer patients who have been prescribed shoes/inserts. This fitting person should be adept at reiterating the physician's messaging about ulcerative risk management and the importance of shoes, inserts, socks, self-care, and (when indicated), remote patient monitoring. Both Siren and Orpyx systems require some investment in time to properly set things up so that their technicians can be considered working under general supervision of the physician and to establish the patterns of patient communication, assurance of HIPAA, as well as the coordination needed for monthly integration of patient communication and billing information.

Patients have to opt-in to be part of a remote patient monitoring program and are responsible for applicable co-payments.

Patient Considerations

Patients have to opt-in to be part of a remote patient monitoring program and are responsible for applicable co-payments. They can only have one parameter monitored at a time. It makes sense for DPMs to only recommend RPM to patients who are capable of working with easy-to-use technology, and who will be receptive to periodic reminders. It doesn't make sense to expend a lot of time trying to convince patients to participate if they are not enthusiastic about a program of self-care and demonstrate a likelihood of dropping out. Approximately one in three patients with diabetes will experience foot ulceration some time in their lives.[1] Patients who have healed a foot ulcer are at greatest risk for re-ulceration. They are patients for whom RPM can provide the greatest benefit and whom practices should first focus on.

Comparing Using Siren and Orpyx

Fitting:

- Set of five socks mailed by Siren to patients based on prescription from DPM.
- One pair of Orpyx insoles dispensed by DPM with shoes. Insoles can be ordered separately from shoes

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or can ship with a pair from Ortho-Feet. Sensor embedded insoles cost $50 per pair.

Onboarding:

• Both Siren and Orpyx utilize trained, tech-savvy personnel to provide patient education, support, and other administrative functions. Siren handles in-house; Orpyx partners with the NavCare company. Both services help patients to set up a 'hub" used for transmitting info from the insoles or socks to the "cloud".

Monitoring:

• Siren transmits information about whether the patient is wearing socks, and the plantar pressure and foot temperature by wirelessly connecting socks to a "hub" plugged into an electrical outlet in the patient's home. Patients do not need a smart phone or home wifi; it's completely cellular.

• They Orpyx system includes a digital display that looks like a cell phone and sends the data to a HIPAA-secure dashboard where the monitor can remotely review the information.

Patient Alerts:

• Siren makes phone calls from in-house licensed practical nurses. Messages are also sent to DPMs for communication with the patient as well.

• Patients using Orpyx receive real-time pressure alerts, step count and hours of use on a provided digital display that looks like a smart phone. Orpyx works with third party provider, NavCare, who has licensed nurses that monitor the patients' data, conduct patient outreach, and communicate with the DPM.

Charging:

• Siren, no need to charge. Set of 5 socks are replaced every 12 months at no charge.

• Orpyx insoles need to be charged by patients every few days using a wireless charger that is placed into the shoes; the insoles need not be removed.

Documentation:

• For both Siren and Orpyx, if the practice allows the RPM company to access the EMR, then monthly notes can be inserted directly into the patient chart. If no access is allowed, the communication notes will be sent through secured HIPAA-compliant messaging to the DPM.

Billing:

• Similar process as for documentation information communicated either to the billing service/manager or to the DPM.

Cost of Monthly Monitoring and Communication:

• Siren, Orpyx approximately $75 per patient per month. Neither company charges DPM the monthly service fee if there is no data being transmitted.

Best Practices from Those Who Have Implemented RPM

Here are suggestions based on what others have learned:

• *Allocate time to get the practice set up with both RPM companies.* This includes creation of patient communication protocols, expectations of when the DPM is to be notified in the event of certain alerts, and how to coordinate with practice charting and billing functions.

• *Become a Certified Siren Provider.* Get trained on how to become an expert in remote patient monitoring and diabetic preventative foot care.

• *Promote that the practice is committed to prevention of DFUs.* Every practice has its own identity and culture. Patients are attracted to places where they believe they will get the best care. Practices should have established protocols where patients with diabetes are scheduled for at least an annual ulcerative risk assessment appointment. This approach can also satisfy Medicare MIPS measures 126 (neurological examination) and 127 (evaluation of footwear and sizing).

• *Combine RPM with an already established routine of annual diabetic ulcerative risk assessment.* When ulcerative risk factors

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such as decreased protective threshold, decreased circulation, increased plantar pressure secondary to musculoskeletal changes or callus in association with neuropathy are detected, patients should be prescribed therapeutic shoes and either prefabricated or custom molded inserts. When there is a history of ulceration, prescribe remote patient monitoring.

- *Use both Siren and Orpyx concurrently.* Orpyx insoles are intended for patients who have mild to moderate foot deformity causing plantar prominence, or those without foot deformities that are at risk of ulceration. Some will not agree to recharge their insoles every few days or will not like the idea of having to carry an additional digital display. For such patients, recommend Siren socks. Sometimes, patients (more commonly women than men) will object to only black or white crew sock style and as such would agree to RPM if provided with a molded insole. Siren socks will soon be available in ankle and dress heights.
- *For patients requiring partial foot filler for partial foot amputation, use Siren socks; available unilaterally.*
- *Replace shoes and inserts annually.* Monthly communication can offer patient reminders to replace insoles every four months and shoes each year.

How DPMs Can Manage an RPM Program

Roles and Responsibilities

DPM: performs diabetic foot risk assessment, prescribes shoes, inserts, RPM.

Shoe/RPM fitter: dispenses shoes with Orpyx RPM insoles.

Billing: receive monthly report from Navcare/Siren informing about patients who have been monitored and communicated with.

Charting: performed by NavCare for Orpyx, Siren LPN, automatically incorporated into patients' EHRs.

Process

- Orpyx: patients' feet scanned, or impression mold taken when diabetic shoes are ordered. If order sent to Orpyx, insoles ship alone; if order sent to OrthoFeet, insoles ship with diabetic shoes. Initial orders accompanied by digital display.
- Siren: Socks and "hub" mailed to patient and patient onboarded based on order sent by physician.

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Benchmarking

Approximately 1/3 of patients with diabetes will experience ulceration at some time in their lifetime.[1] Expect approximately 33 patients to be prescribed RPM for every 100 patients prescribed shoes and inserts. Of those prescribed RPM, expect a split between those with mild to moderate foot deformities for whom Orpyx insoles would be indicated, and those with more significant deformities or partial foot amputation for whom Siren would be the appropriate monitoring device.

Accountability (Metrics)

You cannot manage a program if you cannot measure it. Most practices have the opportunity to provide RPM to over 100 patients, many several times that. A successful wound prevention program can improve the health of hundreds of patients in each practice and creates an opportunity to earn $100,000 or more (Table 1). The physician overseeing the program should, on an ongoing basis, track:

- # Patients enrolled (CPT 99453)
- # Patients monitored (CPT 99457)
- % of patients enrolled for 6 months, 1 year, 2 years
- Revenue collected (99453, 99454, 99457, 99458)
- Revenue collected (A5500, A5501, A5512, A5514, L5000)
- # of CPT 99453 / # of A5500
- Average time if re-ulceration
- Average time if patients discontinue using program

Looking Ahead

By 2050, it's expected that nearly half of all seniors are expected to either have diabetes or be pre-diabetic. RPM offers an approach that can leverage the benefits of diabetic shoes and inserts to promote physical activity while protecting again foot ulceration. While not clear what new technologies lie ahead, there will always be a desire to make utilization easier for patients and practices alike, more accurate monitoring and more effective communication, all done at a lower cost. With such improvement, there is bound to be greater patient and practice adoption of diabetic shoes, inserts, and RPM, leading to improved patient health and lower overall cost. **PM**

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