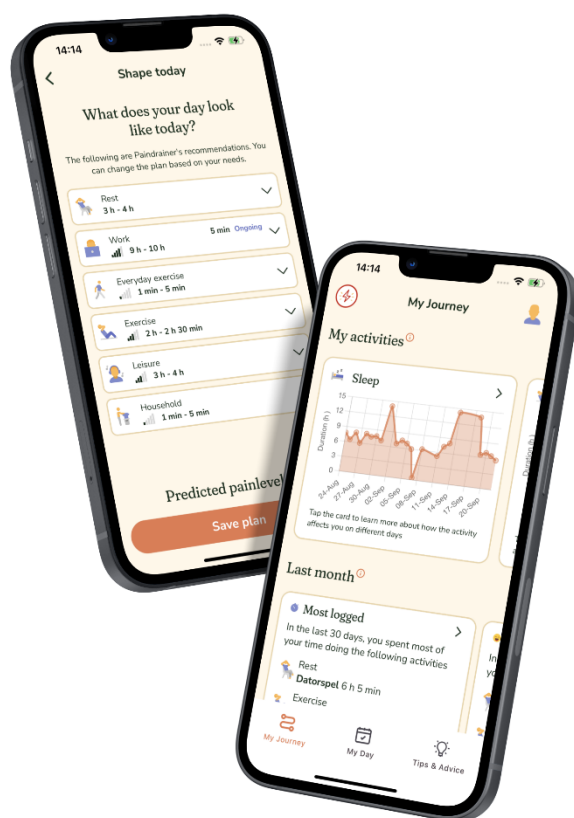


Paindrainer

RTM Playbook





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1. What is RTM?

As defined by the CMS, Remote Therapeutic Monitoring (RTM) refers to the remote monitoring and management of non-physiological patient data. This includes general medicine care, such as the status of a patient's musculoskeletal or respiratory system. It also includes the adherence and response to medication and therapy.

1.1 What is Paindrainer

Paindrainer™ is a digital self-management device, for users with chronic pain, intended to support planning of activities based on the users' individual input of performed activities and pain experience, aiming to alleviate pain.

1.2 RTM at Paindrainer

Paindrainer's RTM solution, PD1, is focused on adherence to medication and therapy. With Paindrainer your clinic can get a state-of-the-art medical device suitable for out-patient setting to provide real time understanding of patient adherence and pain treatment efficacy. The product also supports an in-app chat function with patients, the ability to submit questionnaires, and a resource library that includes general education in the field of pain.

1.3 Intended medical indications:

Chronic pain defined as non-malignant pain that lasts for longer than three months beyond the expected period of healing.

Intended patient population: Adult users with chronic pain, that experiences a correlation between their daily activities and changes in their pain levels.

Intended user profile:

Paindrainer application: Individuals with the ability to use and understand digital application.

Paindrainer Clinical Interface: Health Care Provider (HCP) with patients in treatment for chronic pain.

Intended use environment:

Paindrainer application: Outpatient

Paindrainer Clinical Interface: Primary health care services - general practitioner or doctors specialized in pain treatment, primary health care center or similar out-patient treatment.

Operating principle

Paindrainer application: The user logs in to the Paindrainer™ app using a smartphone or device where the app is downloadable.

The user logs daily activities such as sleep, rest, work, physical activity, household work and leisure time with parameters such as length, intensity and satisfaction. Average experienced pain is also logged daily. The user's daily logs are graphically visualized by the Paindrainer device.

After eight days of consistent daily logging, the device's machine-learning algorithm achieves sufficient training to begin aiding the user in activity planning. With ongoing training, the device progressively enhances its ability to offer precise and personalized suggestions.

The Paindrainer device enables the user to have an iterative process when planning activities. Based on the user's logged activities and pain, the Paindrainer device can also calculate expected pain level as a result of planned activities. User can set individual activity goals.

The application also includes rehabilitation and breathing exercises, along with a curated library of articles on pain management that serves as a knowledge resource for all users.

Paindrainer Clinical Interface: Health care provider (HCP) logs in to Paindrainer interface with a web browser. The clinical interface serves as a dashboard for the HCP to gain insights into patients using the application. It offers a view of each patient's pain experience but also visualizes their adherence to the agreed treatment plan, where applicable.

HCP can set goals for lifestyle changes together with the patient.

1.4 RTM Code structure & Billing

January 1st 2022 CMS approved reimbursement for RTM. The structure of the codes is three folded as described below:

Description	CPT Code	Billing Frequency	2023 CMS rate
Device set up	98975	Once per Episode of care - Initial set-up and patient education on use of RTM device	\$19.38*
Device Supply & Data Transmission	98977	Once per 30-day period - RTM device supply with scheduled recording(s) and/or programmed alert(s) transmission; must monitor a minimum of 16 days of patient data (in total) for each 30 day period	\$55.72*
Treatment Minutes - First 20 mins	98980	Once per 30-day period - First 20 minutes of RTM treatment management services, physician/ other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the 30 day period; first 20 minutes	\$50.18*
Treatment Minutes - Each additional 20 mins	98981	Multiple times per 30-day period - Each additional 20 minutes of RTM treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient/caregiver during the 30 day period; each additional 20 minutes	\$40.84*

* Non-facility national average; exact reimbursement amounts vary by geographic region.

Note that Reimbursable value is based on 2023 CMS RTM rates and may vary by MAC.

The CPT codes 98980 and 98981 can be billed in conjunction with other relevant codes for the patient, such as:

- CCM codes 99487, 99489, 99490, 99491, 99437, and 99439;
- PCM codes 99424, 99425, 99426, and 99427;
- TCM codes 99495 and 99496; and
- BHI services codes 99484, 99492, 99493, and 99494.

It should however be noted that you can not bill for two separate codes under the same period of time.

Providers who are eligible to bill Medicare directly for their services and whose scope of practice includes RTM services are eligible to order and bill for RTM services. This may include:

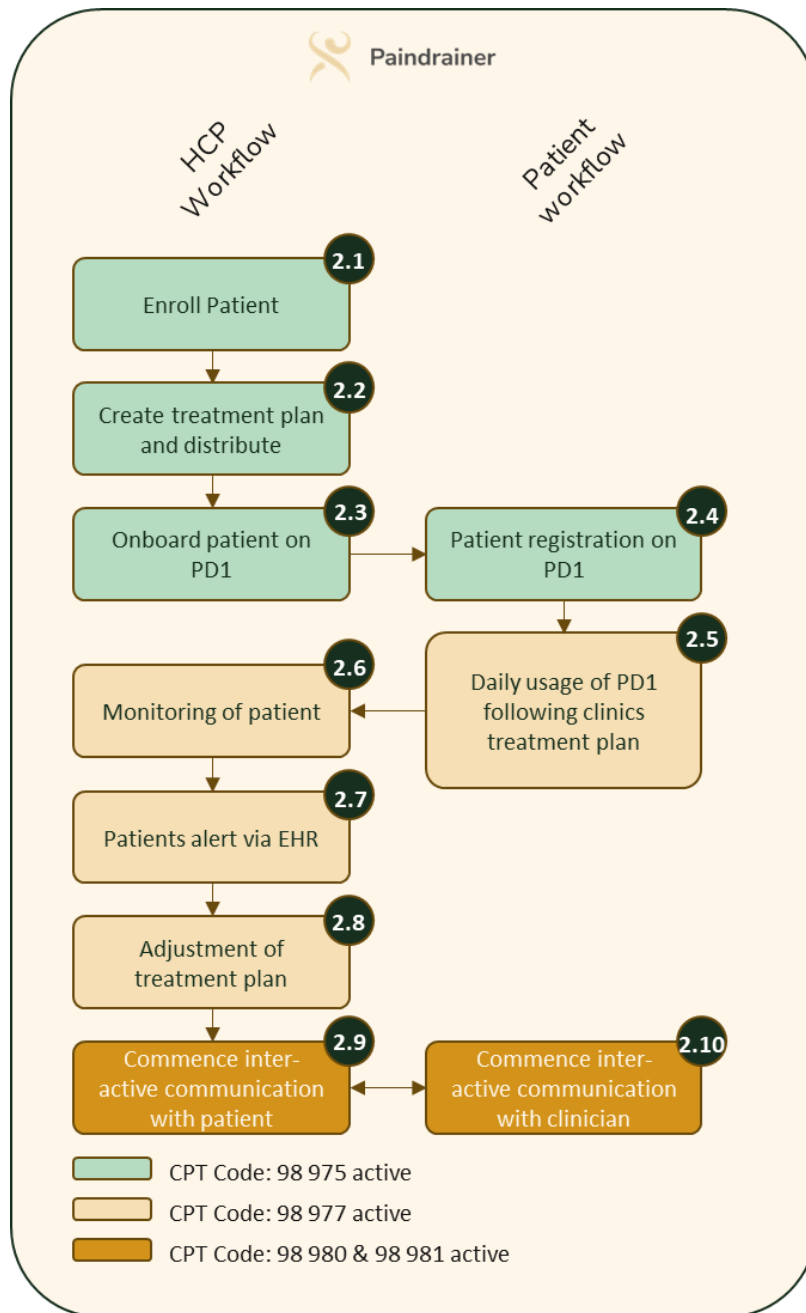
Physicians, Anaesthesiology Assistants, Certified Nurse Midwives, Certified Registered Nurse Anaesthetists, Clinical Nurse Specialists, Clinical Social Workers, Nurse Practitioners, Occupational Therapists in Private Practice, Physical Therapists in Private Practice, Physician Assistants, and Psychologists.

1.4.1 Eligible patients

Eligibility for Remote Therapeutic Monitoring is limited to only two clinical use cases: musculoskeletal and respiratory conditions. Patients must fall under one of these conditions to be eligible. The RTM device must be used to monitor respiratory or musculoskeletal system status, therapy adherence, and/or therapy response.

2. The Paindrainer RTM Process

Below process shows how the Paindrainer, PD1, solution works in relation to the valid CPT codes.



2.1 Enrol Patient

Order and/or document the use of Paindrainer for the appropriate patient in your EMR/EHR system as well as the Paindrainer portal. Note: it is recommended that health care providers document patient enrolment i.e. via a clinical note that support patient eligibility per 1.3.1 and which digital therapeutic, i.e. Paindrainer you are ordering for the patient as an out-patient treatment plan.



2.2 Creating a treatment plan

Within the Paindrainer portal, set relevant treatment plans focusing on daily activity levels, medication, rehabilitation, and other areas relevant for the patient. All areas that are set up will either be directly integrated into patient's device or uploaded as a treatment plan in patient profile page. If Paindrainer is connected with your EHR-system, it can be facilitated this way as well. As part of the treatment plan you also state if it is a 30, 60, 90 days or longer treatment period. In addition to treatment plan you also need to set your clinics criteria for alerts on intervention. The system does not trigger alerts automatically, this needs to be handled by clinic.

2.3 & 2.4 Onboarding of patients

Your clinic has been provided with their own unique patient onboarding page. You will need to onboard the patient on this, either during an in person visit at the clinic, by sending a SMS-link to the patient's phone/email, or by providing them with a physical card with onboarding instructions. If your EHR-system supports transmission of data and has the ability to communicate directly with patients, then that interface can be used instead.

When a patient is onboarded on the device one of the providers health care personnel will introduce the product. As proof that the device was ordered by a physician, the patient need to prior to their first login state their Medical Record number or Insurance Subscriber ID number in the App. When this has been entered, the patient will be able to create a login that includes their personal email and unique password they create.

2.5 Daily patient usages

Remote Therapeutic Monitoring was developed to extend patient care beyond the clinic, RTM assists in providing care beyond the clinical setting, allowing patients to benefit from virtual support between their in-person appointments.

Remote Therapeutic Monitoring was created with the aim of providing enhanced support to musculoskeletal patients in the comfort of their homes and enhancing both outcomes and patient engagement. RTM facilitates increased participation in your comprehensive treatment regimen and enables patients to access virtual assistance between their in-person clinic appointments.

the activity on the Paindrainer device of each patient is tracked by the system, and the number of active days are presented in the Care Portal, giving the health care provider the necessary input to monitor and follow up on your patient.

2.6 & 2.7 Monthly monitoring & Reporting

You will receive information concerning the specific aspects of patient therapeutic monitoring that align with the primary areas of each patient's treatment that you choose to track. In the Paindrainer Care Portal, you will find a standard dashboard for monitoring patients, complete with the capability to activate notifications if you would like to customize and set up specific criteria you would like to be made aware of.

On a monthly basis a billing report is also produced for your clinic providing essential information on the billable amounts for each specific CPT code. This is to be used as support for your billing department when submitting claims.



2.8 Adjustment of treatment plan

Depending on the outcomes observed, you may consider modifying or concluding the existing treatment plan, especially if medication efficacy is found to be inconsistent, daily exercise intensity is progressing too rapidly, and/or other factors that are causing discomfort or pain. These adjustments can be made within the system to promptly update the patient's treatment plan. It's important to note that when you conclude a treatment plan, you should notate this in the system to ensure an accurate audit trail.

2.9 & 2.10 Patient communication

When patient communication is initiated due to a treatment modification or change, it is advisable to engage in a virtual conversation with the patient (i.e. videoconference or chat). Within the Care Portal, you can activate a chat feature to discuss the plan with the patient. All time spent on the chat is automatically recorded, allowing you to monitor when the 20-minute threshold has been reached. If you prefer to conduct an interaction outside of the portal, you should still log into the portal to activate a timer that tracks the time spent with each patient. This step is crucial because accurate interaction data is essential for billing purposes and ensuring a proper record of patient engagement.