ASX ANNOUNCEMENT
29 January 2026

PainChek gains access to US Remote Therapeutic Monitoring (RTM) reimbursement

Highlights

- **Independent US legal opinion confirms PainChek qualifies as an FDA-regulated medical device for Remote Therapeutic Monitoring (RTM) reimbursement through US Centre for Medicare & Medicaid Services (CMS)**
- **PainChek recently granted FDA De Novo classification as a medical device enabling access to the significant musculoskeletal segment of RTM reimbursement framework**
- **PainChek is the only FDA-cleared device capable of assessing pain in non-verbal dementia patients in long-term care settings with musculoskeletal issues, representing 70%+ of residents in long term care[2]**
- **RTM model provides clear economic return to healthcare professionals and represents a significant US growth opportunity for PainChek**
- **The Company will formally launch its RTM initiative to customers and partners at HIMSS 2026 Global Health Conference in Las Vegas, March 9-12th 2026**

Sydney, Australia, 29 January 2026 – PainChek Ltd (ASX: PCK), developer of the world's first AI-powered pain assessment and monitoring application, is pleased to announce that it has received independent legal opinion that the PainChek® device qualifies as an FDA-regulated medical device for the purposes of Remote Therapeutic Monitoring (RTM) reimbursement claims in the United States.

The legal opinion, from leading US healthcare law firm Nixon Law Group, confirms that PainChek meets the statutory definition of a medical device under the US Federal Food, Drug, and Cosmetic Act (FD&C Act) and has been granted De Novo classification by the US Food and Drug Administration (FDA) under 21 C.F.R. 801.109.

As a result, the PainChek Device is eligible to be used by US healthcare professionals when submitting RTM reimbursement claims to the Centers for Medicare & Medicaid Services (CMS).

RTM is a recently introduced CMS reimbursement framework that allows healthcare providers to claim monthly reimbursements for the remote collection and clinical monitoring of therapeutic data associated with the management of musculoskeletal, respiratory and cognitive-behavioural conditions. Importantly, RTM allows for the use of non-physiological and observational data, including pain levels, when collected via an FDA-cleared medical device and incorporated into a prescribed therapeutic plan. The RTM reimbursement in the US is growing rapidly and is projected to be worth US $3bn USD per annum by 2030 with the assessment and management of musculoskeletal diseases being seen as the largest growth sector[1,3]

Philip Daffas, CEO of PainChek said:

"PainChek addresses a significant RTM barrier for healthcare professionals. Until it was cleared as an FDA-approved medical device, there was no medical device available for healthcare professionals to diagnose or treat pain in individuals with moderate to severe dementia. Consequently, musculoskeletal conditions in this cohort were underdiagnosed and healthcare professionals were unable to claim for pain management under RTM reimbursement for this cohort.

"PainChek resolves this issue by objectively detecting pain and linking pain scores to musculoskeletal diagnoses such as osteoarthritis, fractures, joint pain and post-operative musculoskeletal pain. It provides the essential pain assessment and therapeutic response data sets required for healthcare professionals to make RTM reimbursement claims. Furthermore, the PainChek pain assessment process fully aligns with the assessment and monitoring timing requirements linked to the CPT claims rules.

"This positions PainChek as a compliance-ready musculoskeletal RTM enabling device, as well as novel pain assessment medical device."

It is estimated that up to 800,000 residents in US long-term care facilities suffer from musculoskeletal conditions, with a significant proportion also living with moderate to severe dementia. RTM-enabled musculoskeletal monitoring is viewed as a multi-billion-dollar annual opportunity in the United States, with reimbursement paid monthly to healthcare professionals for qualifying monitoring services supported by approved medical devices.

PainChek now operates two complementary US business models:

- Its existing B2B SaaS offering to long-term care facilities, priced at approximately US$50 per bed per annum, representing a market opportunity of around US$150 million per annum; and
- A new RTM reimbursement model that enables recurring revenue through reimbursement-backed clinical use by a broad range of healthcare professionals. A potentially larger revenue opportunity given the monthly reimbursement rates and clear return on investment for healthcare professionals.

The Company is building a detailed PainChek RTM market model and valuation. Based on the available RTM codes (below) if a healthcare professional was billing approximately $150 per month per person by using PainChek, we anticipate earning an appropriate share of this revenue stream.

PainChek also has a US patent extending to 2038 that covers the assessment of pain and monitoring the effect of therapeutic pain treatments which fits in well with the RTM process requirements, providing a long-term competitive barrier in this significantly large marketplace.

PainChek is working with US partners that collectively service more than 25,000 long-term care facilities and healthcare providers to finalise commercial structures and accelerate market penetration under the RTM framework. PainChek is also progressing the expansion of its FDA indications to include home-care

settings, which would extend RTM eligibility beyond long-term care facilities and further broaden the addressable market.

The Company will formally launch its RTM initiative to customers and partners at HIMSS 2026 Global Health Conference in Las Vegas, March 9-12th 2026 and will provide further detail on the go to market strategy in its quarterly ASX investor webinar, scheduled for 10:30am AEDT on 30 January 2026.

Remote Therapeutic Monitoring

Overview

The RTM code set below includes CPT codes 98975, 98976, 98977, 98986, 98979, 98980, and 98981 which are all potentially applicable for healthcare professional claims when using PainChek to assess and manage dementia residents' musculoskeletal pain as a therapeutic response to medication. The CPT Codebook describes the RTM CPT codes as follows:

CPT code	Descriptor	National Monthly Amount*
98975	*Remote therapeutic monitoring (e.g., therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment*	$19.73
98976	*Device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period*	$51.44
98977	*Device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period*	$51.44
98979	*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes*	$26.39
98980	*Remote therapeutic monitoring treatment management services, physician or other qualified health care professional requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 20 minutes*	$50.14
98981	*Remote therapeutic monitoring treatment management services, physician/other qualified health care professional time in a calendar month requiring at least one interactive communication with the parent/caregiver during the calendar month; each additional 20 minutes*	$39.14

Amounts listed are the National Payment Amounts current as of the date of this memo. Actual reimbursement rates may vary across geography and are subject to change by CMS at any time. For more information regarding current fee schedule amounts, please see the CMS Physician Fee Schedule Online Lookup Tool.

1. https://www.databridgemarketresearch.com/reports/us-remote-therapeutic-monitoring-msk-market
2. https://link.springer.com/article/10.1007/s41999-024-01067-x
3. https://www.strategicmarketresearch.com/market-report/digital-musculoskeletal-care-market

This announcement has been approved for release by the Board.

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About PainChek

PainChek® is the world's first regulatory-cleared medical device for the assessment of pain, enabling best-practice pain management for people living with pain in any environment, from those who cannot reliably self-report their pain, those who can, and for those whose ability to self-report their pain fluctuates.

The PainChek® app is available on smartphones and tablets and combines PainChek's AI pain assessment tool, which intelligently automates the multidimensional pain assessment process, with the Numerical Rating Scale (NRS). This hybrid functionality allows accurate, consistent pain assessment at the point of care, and for care to be considered in PainChek's detailed reporting suite, PainChek® Analytics.

Globally, PainChek® has attained regulatory clearance as a medical device in Australia, USA, Canada, the European Union, New Zealand, Singapore, Malaysia, and the United Kingdom.

PainChek® has contracts with over 2,000 aged care facilities, with more than 17,000,000 digital pain assessments conducted to date, and is trusted by thousands of nurses, carers, and clinicians.

Using PainChek®, facilities can:

- Ensure greater consistency, continuity, and diagnostic certainty in pain assessment and management by decreasing subjectivity and removing unintentional assessor bias
- Streamline the pain assessment process for time-poor carers, with access to the PainChek® tool, the NRS, pain trends, and charting in one solution
- Simplify record-keeping and documentation to demonstrate compliance and support funding claims, with all historical pain assessment data in one place
- Enhance engagement with GPs and allied healthcare professionals

Clinical studies conducted in Australian and UK residential aged care centres have been published in various peer-reviewed journals including the Journal of Alzheimer's Disease. An article in BMC Geriatrics indicates that PainChek® is a valid and reliable instrument to assess the presence and severity of pain in people with moderate-to-severe dementia living in aged care. Further information on clinical studies can be found here.

PainChek® has successfully supported accurate pain assessment and management for thousands of adults worldwide living with dementia, disability, or other conditions impacting their ability to self-report pain. Building on the success of this technology, the clinically validated PainChek® Infant app identifies and detects six facial action units indicative of pain in infants aged one month to 12 months.

The need for PainChek as a best-practice pain management solution also extends to older people living at home and with access to home care packages that enable long-term home living. PainChek is expanding into home care by partnering with home care and disability service providers.

For more information, visit: https://painchek.com