

Adherium advocates position on new Remote Therapeutic Monitoring reimbursement and criteria to U.S. Centers for Medicare and Medicaid Services

Melbourne, Australia – 8 October 2021: Adherium Limited (ASX: ADR), a leader in respiratory eHealth, remote monitoring and data management solutions, submitted commentary to the U.S. Centers for Medicare and Medicaid Services on the proposed new Current Procedural Terminology (CPT®) codes for Remote Therapeutic Monitoring.

The U.S. Centers for Medicare and Medicaid Services (CMS) proposed five new CPT codes for Remote Therapeutic Monitoring (RTM) of “non-physiologic” patient data such as “respiratory system status, therapy (medication) adherence, and therapy (medication) response.” CMS solicits public input to Proposed Rules and carefully considers these comments prior to publishing Final Rules.

“This is a potentially important development for our business as the CMS fee schedule is critical to driving market adoption of technological innovation in digital health, and would be complementary to our existing route to enabling reimbursement under Remote Physiologic Monitoring codes through incorporating physiological measures into our Hailie® sensors,” explained Rick Legleiter, Adherium’s Chief Executive Officer. “Healthcare is at a global tipping point for smart medicine and medical IoT. As such it is important that Adherium assert thought leadership with U.S. policy makers on remote monitoring and eHealth. We engaged and directly contributed with our comment submission to CMS during the rule making process advocating for patients, providers and digital health affiliates.”

Mr Legleiter added, “we expect the Final Rule to be published between mid-November and early-December at which time we will know the specific policy criteria and reimbursement rates to understand and assess the market opportunity. The policy is then expected to go into effect on 1 January 2022.”

The new RTM codes closely resemble the existing Remote Physiologic Monitoring (RPM) codes with one code for patient set-up and education on the use of RTM equipment, one device code for data transmission of respiratory system status, and two service codes for monitoring patient data and managing treatment. While the RPM codes relate to physiologic data, CMS specifies in the Proposed Rule that the RTM codes are intended to cover monitoring of “non-physiologic data.” CMS does not specifically define “non-physiologic data,” but notes that RTM should be used to monitor health conditions through data capture. The proposed RTM codes attempt to fill some important gaps in current RPM coverage for patients, providers, and digital health companies.

Summary regarding the Adherium commentary and the CMS rule making process are outlined in the Appendix below. Additional updates will be provided as information becomes available.

Adherium’s full CMS comment submission may be accessed on its website at https://www.adherium.com/media/1757/adherium-2022-mpfs-comments-on-rtm_sept_11_2021.pdf

About Adherium (ASX: ADR)

Adherium is a provider of digital health solutions and a global leader in connected respiratory medical devices, with more than 170,000 sold globally. The Company develops, manufactures and supplies a broad range of connected medical devices for respiratory medications for patients, pharmaceutical companies, healthcare providers and contract research organisations. Adherium’s Hailie® solution is designed to help patients achieve better adherence and provide visibility to parents and caregivers. It does this by tracking medication use and reminding the user with helpful nudges when it is time to take doses, and by providing access to usage history to better understand patterns in their asthma and COPD.



Learn more at www.adherium.com

This ASX announcement was approved and authorised for release by the Board of Adherium.

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APPENDIX

Adherium's comment submission is summarised below focusing on reimbursement and the policy criteria that CMS should...

- clarify that both RTM and Remote Physiological Monitoring (RPM) can be billed concurrently so long as the requirements for each are met separately.
- clarify that the RTM CPT codes, as currently proposed, DO allow therapists and other QHCPs (Qualified Healthcare Providers) who can independently bill Medicare to order and bill for RTM. CMS should also clarify that pharmacists are QHCPs for purposes of RTM.
- align the coding constructs for RPM and RTM by finalizing, on an interim basis, a set of additional Healthcare Common Procedure Coding System G-codes for RTM that mirrors the current code descriptors for the RPM Evaluation and Management CPT code set and designate those codes as "care management services" (explanatory note: temporary G codes are assigned to services and procedures that are under review before being included in the CPT coding system.).
- restrict the RTM code sets to the same minimum thresholds as RPM for a minimum 16 days monitored within a 30-day period.
- allow for reimbursement codes 989X2 and 989X3 to be billed once per device supplied to the patient to track "total adherence".
- require automated data reporting and should NOT allow self-reported data for medication adherence monitoring.
- recategorize Software as a Medical Device (SaMD) and ongoing maintenance of SaMD as direct practice expenses (dPE).

As background, Current Procedural Terminology (CPT) code set is maintained by the American Medical Association. The CPT codes describe medical, surgical, and diagnostic services designed to standardise information on medical services and procedures among providers, patients, and payers for administrative, financial, and analytical purposes. The use of the code set is mandated by almost all U.S. health insurance payment and information systems, including CMS.



CMS is a federal agency within the United States Department of Health and Human Services (HHS) that administers the Medicare program and works in partnership with state governments to administer Medicaid along with other programs and responsibilities.

On 13 July 2021 CMS released its proposed Medicare Physician Fee Schedule for Calendar Year 2022 (the “2022 Proposed MPFS” or the “Proposed Rule”). In doing so, it recognised five new RTM CPT codes of “non-physiologic” patient data such as mentioned earlier for “respiratory system status, therapy (medication) adherence, and therapy (medication) response”.