Device Adherence Supporting Literature

Annotated Reference List Version 1.0

This reference list is for device providers and payers evaluating the evidence base for medical device adherence as a value-based opportunity. Articles discussing specific devices can be used in initial cost study analytics and for framing opportunities to leadership. Regulatory context can be used for larger strategic framing against organizational goals in alignment with CMMI models.

Each entry includes the full citation, a summary, conclusion, and a key takeaway relevant to structuring an adherence program.

Value-Based Payment Policy & Regulatory Context

1. The PROMETHEUS Bundled Payment Experiment

Hussey, P.S.; Ridgely, M.S.; Rosenthal, M.B. The PROMETHEUS bundled payment experiment: Slow start shows problems in implementing new payment models. Health Aff. 2011, 30, 2116–2124. https://doi.org/10.1377/hlthaff.2011.0784

Summary	Evaluated the early rollout of PROMETHEUS Payment, one of the first bundled-payment pilots tied to the Affordable Care Act's push toward episode-based payment. As of May 2011, none of the three pilot sites had executed contracts or made an actual bundled payment.
Conclusions	The pilots took far longer to implement than planned, largely because bundled payment is complex to layer onto existing fee-for-service claims infrastructure. Participants still saw promise in the model despite the slow start.
Key Takeaway	Even well-designed alternative payment models face a long, claims-infrastructure-dependent runway before they generate real payments - useful for setting realistic timelines on new VBC arrangements.

2. Federal Budgetary Effects of CMMI

Congressional Budget Office. Federal Budgetary Effects of the Activities of the Center for Medicare & Medicaid Innovation; Publication No. 59612; CBO: Washington, DC, USA, 2023. https://www.cbo.gov/publication/59612

Summary	CBO's most recent analysis of the Center for Medicare & Medicaid Innovation (CMMI), updating its original 2010 projection that CMMI's models would produce net federal savings.
Conclusions	CBO now estimates that CMMI's activities increased net federal spending during its first decade of operation and projects continued net cost in its second decade - a reversal of the original savings projection.
Key Takeaway	The federal government's own scorekeeper has found mixed-to-negative net budget results from a decade of value-based care experimentation, underscoring that a program's credibility rests on demonstrated dollar impact, not framing alone.

3. MSSP - Pathways to Success Final Rule

Centers for Medicare & Medicaid Services. Medicare Shared Savings Program; Accountable Care Organizations - Pathways to Success [Final rule]. Fed. Regist. 2018.

Summary	Final CMS rule overhauling the Medicare Shared Savings Program (MSSP), redesigning ACO participation tracks to move organizations more quickly into two-sided (risk-bearing) arrangements.
Conclusions	CMS concluded the prior structure let too many ACOs remain in low-accountability, shared-savings-only tracks. The redesigned “Pathways to Success” structure was projected to increase net savings to Medicare over the following decade.

Key Takeaway	Regulatory direction in Medicare's flagship ACO program has moved toward accountability for both savings and losses - device providers entering VBC arrangements should expect performance-risk expectations, not just upside-only shared savings.

4. CMS Innovation Center 2021 Strategic Direction

Centers for Medicare & Medicaid Services, Innovation Center. Innovation Center Strategy: 2021 Strategic Direction; CMS: Baltimore, MD, USA, 2021. https://www.cms.gov/priorities/innovation/about/2021-strategic-direction

Summary	CMS Innovation Center's ten-year strategic refresh, setting five objectives - Drive Accountable Care, Advance Health Equity, Support Innovation, Address Affordability, and Partner to Achieve System Transformation - to guide its model portfolio through 2030.
Conclusions	CMS committed to streamlining its model portfolio and set a goal that all Medicare fee-for-service beneficiaries, and the vast majority of Medicaid beneficiaries, be in a care relationship with accountability for quality and cost by 2030.
Key Takeaway	Accountability for cost of care is an explicit, named federal policy goal through 2030 - this is the strategic backdrop any device-adherence value-based pitch should align to.

CPAP / Sleep Apnea Evidence

5. CPAP Adherence and Inpatient Utilization (Medicare, CVD)

Wickwire, E.M.; Bailey, M.D.; Somers, V.K.; et al. CPAP adherence is associated with reduced inpatient utilization among older adult Medicare beneficiaries with pre-existing cardiovascular disease. J. Clin. Sleep Med. 2022, 18, 39–45. https://doi.org/10.5664/jcsm.9478

Summary	Retrospective analysis of a 5% random sample of Medicare claims (n=1,921) among beneficiaries aged 65 and older with pre-existing cardiovascular disease (CVD) who began CPAP therapy for newly diagnosed obstructive sleep apnea (OSA), comparing healthcare utilization across low, partial, and high CPAP adherence over 24 months.
Conclusions	Higher CPAP adherence was associated with reduced inpatient healthcare utilization among this Medicare population with CVD.
Key Takeaway	In a Medicare CVD population, the level of device adherence tracked directly with inpatient utilization - exactly the kind of claims signal a payer-facing adherence program needs to demonstrate.

6. CPAP Adherence and Treatment Cost (OSA and CVD)

Bock, J.M.; Needham, K.A.; Gregory, D.A.; Ekono, M.M.; Wickwire, E.M.; Somers, V.K.; Lerman, A. Continuous positive airway pressure adherence and treatment cost in patients with obstructive sleep apnea and cardiovascular disease. Mayo Clin. Proc. Innov. Qual. Outcomes 2022, 6, 166–175. https://doi.org/10.1016/j.mayocpiqo.2022.01.002

Summary	Studied Medicare fee-for-service patients with CVD and OSA, comparing total episode-of-care costs between CPAP-adherent (treatment evidenced 91 or more days after initiation) and non-adherent patients using durable medical equipment claims.
Conclusions	Adherent patients had significantly lower total episode-of-care costs ($6,825) than non-adherent patients ($11,312) - roughly a 40% reduction - driven mainly by fewer outpatient expenses.
Key Takeaway	A directly quantified cost comparison: CPAP adherence was associated with a ~40% reduction in annual healthcare-related costs in Medicare patients with CVD and OSA - a concrete figure for a payer conversation.

7. PAP Adherence, Utilization, and Costs in OSA and Obesity

Sert Kuniyoshi, F.H.; Cameron, A.; Pépin, J.-L.; Dexter, R.B.; Woodford, C.; Cistulli, P.A.; Alpert, N.; Sterling, K.; Malhotra, A. Adherence to positive airway pressure therapy and healthcare resource utilization and costs among patients with obstructive sleep apnea and obesity. Int. J. Obes. 2026. https://doi.org/10.1038/s41366-025-01985-1

Summary	Large retrospective cohort (n=173,691) linking payer claims data to objective cloud-connected PAP usage data, comparing ER visits, hospitalizations, and costs across adherent, intermediately adherent, and nonadherent patients with obesity and newly diagnosed OSA over two years.
Conclusions	Adherent patients had significantly fewer ER visits and hospitalizations and lower total healthcare costs than nonadherent patients in both year 1 (~$595 lower) and year 2 (~$695 lower), with intermediately adherent patients falling in between - indicating a dose-dependent relationship.
Key Takeaway	The dose-dependent finding matters for program design: even partial adherence improvement, not just full compliance, is associated with measurably better cost and utilization outcomes.

NPWT / Wound Care Evidence

8. NPWT After Partial Diabetic Foot Amputation (RCT)

Armstrong, D.G.; Lavery, L.A. Negative pressure wound therapy after partial diabetic foot amputation: A multicentre, randomised controlled trial. Lancet 2005, 366, 1704–1710. https://doi.org/10.1016/S0140-6736(05)67695-7

Summary	Multicenter, 16-week randomized controlled trial (n=162) comparing negative pressure wound therapy (NPWT) to standard moist wound therapy for post-amputation diabetic foot wounds.
Conclusions	NPWT was associated with a higher proportion of healed wounds, faster healing rates, and fewer complications than standard care.
Key Takeaway	This is the foundational RCT establishing NPWT's clinical superiority for diabetic foot wounds - the clinical basis the economic analysis below (source 9) builds its cost case on.

9. Resource Utilization and Economic Costs of NPWT

Apelqvist, J.; Armstrong, D.G.; Lavery, L.A.; Boulton, A.J.M. Resource utilization and economic costs of care based on a randomized trial of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. Am. J. Surg. 2008, 195, 782–788. https://doi.org/10.1016/j.amjsurg.2007.06.023

Summary	Post hoc economic analysis of the same 162-patient trial, comparing resource utilization (clinic visits, dressing changes, surgical procedures) and direct costs between NPWT and standard moist wound therapy.
Conclusions	NPWT was associated with lower resource utilization and lower overall cost of care. The cost difference favoring NPWT exceeded $8,000 for patients treated at least 8 weeks, and over $12,500 for patients who achieved full wound closure.
Key Takeaway	A directly quantified economic case for NPWT - this is the type of resource-utilization and cost-offset study a program should be building for other device categories.

10. Remote Monitoring Saves Costs in Outpatient NPWT

Griffin, L.P.; Sifuentes, M.M. Remote monitoring saves costs in outpatient negative pressure wound therapy. Am. J. Manag. Care 2022, 28, 53–58. https://doi.org/10.37765/ajmc.2022.88738

Summary	Retrospective cohort study of patients using NPWT with (n=675) or without (n=430) remote therapy monitoring (RTM) in the postacute outpatient setting, comparing 90-day wound-related costs.
Conclusions	After adjusting for confounders, the RTM group had lower adjusted 90-day wound-related costs than the non-RTM group. RTM patients had higher NPWT-specific costs but lower non-NPWT wound-related costs.
Key Takeaway	A direct precedent for the “adherence monitoring lowers non-device costs” argument: remote monitoring paid for itself through lower non-device wound-related spend, even though it increased device-specific cost.

Diabetes Technology (CGM / Insulin Delivery) Evidence

11. Hybrid Closed-Loop Systems for Type 1 Diabetes

Asgharzadeh, A.; Patel, M.; Connock, M.; et al. Hybrid closed-loop systems for managing blood glucose levels in type 1 diabetes: a systematic review and economic modelling. Southampton (UK): National Institute for Health and Care Research; 2024 Dec. (Health Technology Assessment, No. 28.80.)
https://www.ncbi.nlm.nih.gov/books/NBK610297/ doi: 10.3310/JYPL3536

Summary	A UK National Institute for Health and Care Research (NIHR) health technology assessment, commissioned on behalf of NICE, combining a systematic review of clinical evidence with economic modelling of hybrid closed-loop (continuous glucose monitor plus insulin pump) systems for managing type 1 diabetes.
Conclusions	The review found that hybrid closed-loop systems have the potential to improve outcomes for people with type 1 diabetes and their families, and the accompanying economic model was built to assess their cost-effectiveness for NICE's technology appraisal process.
Key Takeaway	This is the highest evidence-maturity precedent for CGM/insulin delivery in this list and can be considered a useful foundation for building out a future CGM/Pump adherence-cost case study.

12. Glycemic Control and Diabetes-Related Hospital Costs

Menzin, J.; Korn, J.R.; Cohen, J.; Lobo, F.; Zhang, B.; Friedman, M.; Neumann, P.J. Relationship between glycemic control and diabetes-related hospital costs in patients with type 1 or type 2 diabetes mellitus. J. Manag. Care Pharm. 2010, 16, 264–275.
https://doi.org/10.18553/jmcp.2010.16.4.264

Summary	Retrospective cohort study assessing the relationship between glycemic control (HbA1c), diabetes-related hospitalizations, and hospital costs among adult patients with type 1 or type 2 diabetes affiliated with a managed care organization's primary care clinic.
Conclusions	Based on how this study is described in later citing literature, higher mean HbA1c levels were associated with significantly higher estimated hospitalization costs, though the odds of having any diabetes-related hospitalization were not significantly elevated except at very high HbA1c levels (≥10%).
Key Takeaway	Glycemic control (a proxy for adherence to insulin or CGM-guided therapy) tracks with hospitalization cost even when it doesn't always change whether a hospitalization happens, supporting a cost-severity argument rather than just a utilization-frequency argument.

Market & Cost Context

13. How Much and Why ACA Marketplace Premiums Are Going Up in 2027

Peterson-KFF. Health System Tracker.
https://www.healthsystemtracker.org/brief/how-much-and-why-aca-marketplace-premiums-are-going-up-in-2027

Summary	Peterson-KFF analysis of 2027 rate filings from 276 insurers across all 50 states and DC participating in ACA Marketplaces.
Conclusions	Insurers are proposing a median premium increase of 15% for 2027, the second consecutive year of double-digit increases. Rising healthcare service costs, the expiration of enhanced premium tax credits, and a resulting sicker risk pool are cited as the primary drivers.
Key Takeaway	This is market context, not a device-adherence study - it shows payers are under real, compounding cost pressure right now, which reinforces the urgency of any credible cost-offset case a device-adherence program can bring them.