

# Virtual Musculoskeletal Solutions

HEALTH TECHNOLOGY ASSESSMENT | JUNE 2024 | V1.2



**PHTI.org** 

# About This Report

**The Peterson Health Technology Institute (PHTI)** provides independent evaluations of innovative healthcare technologies to improve health and lower costs. Through its rigorous, evidence-based research, PHTI analyzes the clinical benefits and economic impact of digital health solutions, as well as their effects on health equity.

These evaluations inform decisions for providers, patients, health plans, and investors, accelerating the adoption of high-value technology in healthcare.

PHTI focuses on health technologies designed to replace or augment traditional care delivery, including digital therapeutics, chronic care management apps, and remote patient monitoring technologies.

## The Peterson Health Technology Institute

PHTI was founded in 2023 by the Peterson Center on Healthcare, a nonprofit organization dedicated to making higher-quality, more affordable healthcare a reality for all Americans. PHTI and the Center are wholly owned subsidiaries of, and are funded entirely by, the Peter G. Peterson Foundation. PHTI does not accept financial contributions.

## PHTI selects assessment topics based on the:

- Burden of disease to the healthcare system;
- Investment and innovation in the digital health technology;
- Body of evidence about the effectiveness of the technology; and
- Stakeholder interest (purchasers, providers, and patients).

PHTI assessments evaluate evidence of the clinical and economic impact of these technologies using the ICER-PHTI Assessment Framework for Digital Health Technologies, which was designed by a team of experts specifically for digital health products and solutions. This is a secondary research review that relies on published literature and information, as well as proprietary data submitted directly from companies. PHTI did not conduct original testing of the products. All companies included in this report were notified and given an opportunity to submit clinical, commercial, and/or economic data, which were included in the evaluation if eligible.

The economic models used in this report are intended to compare clinical outcomes and expected costs at the population level. Model results represent average findings and should not be presumed to represent cost or outcomes for any specific patient or payer.

The findings and recommendations contained within this report represent the opinions of PHTI based on the information considered in this assessment. The findings are current as of the date of publication. Readers should be aware that new evidence may emerge following the publication of this report that could influence the results. Virtual musculoskeletal (MSK) solutions are likely to evolve over time, which may impact their performance. PHTI may revisit its analyses in updates to this report in the future.

#### V1.2 was posted on July 29, 2024.

It includes updated study counts that do not alter the findings and information about additional company-submitted economic impact analyses.

V1.1 was posted on June 12, 2024.

It includes an updated Exhibit 5 to reflect that Omada does not use coaches and added introductory context about the solution-specific evidence on healthcare savings (p. 49).

# Table of Contents

## 4

#### Introduction

- 4 Letter From the Executive Director
- **Report Contributors and Reviewers** 5
- 6 **Executive Summary**
- 10 The Case for Innovation

## 11

#### **Technology Context**

- 12 Standard of Care for MSK Disorders
- 14 Barriers to In-Person PT
- 15 Patient Perspective
- 16 Virtual MSK Solutions

## 22

#### **Clinical Effectiveness**

 $\rightarrow$ 

- 22 Systematic Literature Review
- 27 Pain and Function as Primary Health Outcomes
- 32 Secondary Outcomes
- 37 Solution-Specific Analysis
- 42 Clinical Effectiveness Ratings

## 43

## **Economic Impact**

43 Budget Impact Model Methodology

 $\rightarrow$ 

 $\rightarrow$ 

 $\rightarrow$ 

46 Budget Impact Model Results

## 51

### **Summary Ratings**

## 53

#### **Next Steps**

- 53 Realizing Full Potential of Virtual **MSK Solutions**
- 53 Recommendations for Innovators
- 54 Recommendations for Purchasers
- 55 Recommendations for Providers

## 56

List of Appendices	$\rightarrow$

57

$\rightarrow$

## $\rightarrow$

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# Letter From the Executive Director

More than one in three Americans experience MSK problems that impact their daily lives, affect their ability to work and earn a living, and contribute to high medical spending. As the U.S. population ages and the demand for MSK services continues to grow, technologies that provide convenient, scalable, and affordable MSK care hold promise for those in need.

PHTI's mission is to accelerate the adoption of high-value healthcare technologies, and this particular report hit home for me personally. In 2023, I suffered a serious broken leg that left me with pain and limited mobility for almost a year. During that period, I crutched and hobbled my way to three in-person physical therapy (PT) sessions per week — squeezing in sessions on busy workdays and unfortunately regularly missing them during business travel. Virtual PT would have been a great option for me. Yet, I never realized that my insurance covered a virtual MSK program — the providers were not listed in my network and my doctor never suggested it.

If someone like me — who works day in and out on healthcare, was uninformed — I can only imagine how many millions of people are in need of more information about this important area of healthcare innovation. As more employers and health plans adopt virtual MSK solutions, we all need a clear understanding of which therapy options work best for which patients and for which MSK conditions.

Clinically effective solutions — those that demonstrate similar health benefits to in-person PT — stand to improve patient outcomes, convenience, and quality of life. They can reduce transportation burdens for patients, which in turn can improve the speed with which they initiate PT, and also their adherence to the exercise program. Evidence tells us that these factors are very important to accelerate healing and reduce the need for surgeries and other complex treatments.

Economically, virtual MSK solutions also have the potential to use technology, including AI, to scale their services with greater efficiency than traditional in-person care. By integrating the technology solution with oversight from licensed physical therapists, these virtual solutions have the potential to deliver therapy at lower cost because they have reduced physical, overhead, and human capital costs.

The virtual MSK solutions described in this report seek to provide meaningful clinical and economic benefits. They treat patients with serious pain, functional limitations, and medical needs in a convenient and efficient way that can improve access and compliance. To realize the full potential of virtual MSK solutions, we need better data to understand which patients and conditions stand to benefit most from virtual PT. These solutions should also be integrated more closely into medical benefits (rather than wellness benefits) to enable coordination with referring physicians and effective management of care. We hope that this report helps payers, providers, and innovators advance these valuable solutions to realize their full promise to improve health outcomes and reduce medical spending.

Sincerely,

Carol Pear

**Caroline Pearson, Executive Director** Peterson Health Technology Institute

# Report Contributors and Reviewers

PHTI partners with a diverse set of contributors, advisors, and stakeholders. Those who directly contributed to this report are listed below. See our <u>website</u> for a full list of <u>partners</u> and <u>advisors</u>, including our Advisory Board and Purchaser Advisory Council, who offer general guidance but do not participate in the assessment process.

### **Clinical Advisors**

The following clinical advisors provided expertise about usual clinical care for MSK conditions, virtual solutions, and primary and secondary health outcomes. The clinical advisors have no relevant conflicts of interest to disclose.

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- Alex Jahangir, MD Professor and Vice-Chair, Department of Orthopedic Surgery; Director, Division of Orthopedic Trauma, Vanderbilt University Medical Center

Report contributors and reviewers provided important expertise and insight throughout our process. PHTI is solely responsible for the report and its findings.

#### **Evaluation Partners**

The following independent evaluation partners contributed to this report. The evaluation partners have no relevant conflicts of interest to disclose.

- <u>Curta</u> assessed the clinical and economic impact of these technologies using the published Assessment Framework, including the systematic literature review and budget impact assessment.
- <u>Charm Economics</u> developed insight into how different technologies work, what they cost to deliver, and their impact on patients and purchasers.
- <u>The Institute for Clinical and</u> <u>Economic Review (ICER)</u> codeveloped the <u>ICER-PHTI</u> <u>Assessment Framework</u> <u>for Digital Health Technologies</u>, and was consulted to review its implementation in this report.

### **Other Partners**

<u>Manatt Health</u> provided consulting, research, and operational support throughout the development of the report.

### **Patient Perspectives**

PHTI conducted focus groups and interviews with seven patients with MSK conditions who had experience with virtual MSK solutions. Patients were recruited for diversity across age, gender, race and ethnicity, income level, geography, and insurance type.

## **Company Submissions**

PHTI directly engaged companies included in the report and accepted submissions of public and proprietary information to inform the assessment. PHTI did not conduct any primary analysis of patient data. PHTI applied the same standards for minimum evidence requirements and risk of bias reviews to company-submitted information as to all other studies included in the report. Companies did not influence the assessment methods or findings. Clinical Effectiveness Economic Impact Summary Ratings Next Steps

# **Executive Summary**

Virtual musculoskeletal (MSK) solutions aim to expand access to care — particularly virtual, exercise-based physical therapy (PT) — that can improve pain and functional status for people with a range of MSK disorders. By making care more available and convenient, these solutions aim to improve patient outcomes and avoid unnecessary treatment, including surgery, injections, imaging, and pain medication.

These solutions vary in the technology they use, the degree of clinician involvement, and how they integrate with traditional in-person care models. The solutions in this report are assessed in three categories:

- **1 App-based exercise therapy solutions** provide self-directed exercise therapy using care plans that are primarily designed and updated by algorithms, based on data from computer vision analysis or on-body motion sensors. In these solutions, there is limited physical therapist involvement once an exercise program is established.
- Physical therapist-guided solutions offer virtual PT with a higher level of clinical involvement when onboarding participants, designing exercise therapy regimens, and managing their care. These offerings generally include self-directed exercise programs with feedback from computer vision and/or on-body sensors. They also offer more frequent human interaction with coaches and physical therapists through both video visits and asynchronous communication.
- **Remote therapeutic monitoring (RTM)-augmented PT solutions** supplement in-person PT with virtual care. These solutions support patients with self-directed exercises between in-person sessions and enable physical therapists to monitor their patient's progress remotely. The primary in-person physical therapist continues to direct care and may bill for the use of these solutions via RTM billing codes.

App-based exercise therapy and physical therapist-guided solutions generally aim to replace in-person care, whereas **RTM-augmented PT solutions** are meant to supplement in-person care by improving adherence to care plans between in-person PT visits. PHTI assessed clinical outcomes of patients using these virtual MSK solutions, including improvements in pain, function, and adherence, as well as their economic impact compared with in-person PT.

#### **Included Solutions**

The solutions evaluated in this assessment were identified through a wide initial scan of the virtual MSK management space using market analysis platforms and published literature. A company-by-company analysis then examined eligible products and grouped those with similar characteristics, mechanisms of action, customers, and value propositions. Included solutions are those sold by DarioHealth, Hinge Health, Kaia Health, Limber Health, Omada Health, RecoveryOne, Sword Health, and Vori Health.

#### Stakeholder Engagement

PHTI solicits input and advice from a diverse set of stakeholders, including health plans, employers, providers, digital health developers, and investors. During the assessment process, PHTI partnered with clinical advisors, experts in health technology assessment, and health economists. PHTI also conducted direct qualitative research with patients. All companies included in the report were given an opportunity to submit clinical, economic, and other commercial information to inform the assessment.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

#### Exhibit 1

#### ASSESSMENT OF VIRTUAL MSK SOLUTIONS

WHAT IS THE GOAL OF THE TECHNOLOGY?	/irtual MSK solutions seek to expand or patients and avoid unnecessary tre	convenient access to virtual PT to impr eatment and spending.	ove pain and functional status
WHICH CATEGORIES ARE INCLUDED?	App-Based Exercise Therapy Solutions Dario, Kaia	Physical Therapist–Guided Solutions Hinge, Omada, RecoveryOne, Sword, Vori	RTM-Augmented PT Solutions Limber
WHAT ARE THE CLINICAL BENEFITS?	<ul> <li>App-based exercise thera</li> <li>Physical therapist—guide with in-person PT.</li> <li>RTM-augmented PT solur and function compared to</li> </ul>	<b>py solutions</b> are shown to improve patie <b>d solutions</b> can improve patients' pain a t <b>ions</b> have limited but positive evidence i in-person PT alone.	nts' pain compared with no in-person PT. nd function at a level comparable ndicating superior outcomes for pain
WHAT IS THE BUDGET IMPACT?	<ul> <li>Absent sufficient p exercise therapy s</li> <li>At current prices, p PT and generate sa</li> <li>RTM-augmented F avoided care do no</li> </ul>	ricing data, this report does not estima olutions. hysical therapist—guided solutions can wings from avoided care. PT solutions increase total healthcare sp t offset increased costs of RTM billing.	te the budget impact of <b>app-based</b> decrease spending relative to in-person pending because estimated savings from
WHICH TARGET POPL COULD BENEFIT MOS	JLATIONS Virtual MSK so barriers to in- with mobility l	olutions stand to improve access for po person PT, including older adults, peop imitations.	pulations who otherwise have le who live in rural areas, and those
WHERE ARE THERE O TO OPTIMIZE THESE S	PPORTUNITIES Integra SOLUTIONS? medica	e into Encourage PT-first I benefits with virtual care as an option	Pursue Improve value-based evidence contracts generation

#### **PHTI Analysis**

This evaluation has two primary components — clinical effectiveness and economic impact.

**Clinical effectiveness:** The systematic literature review screened more than 2,000 pieces of evidence. In addition, five companies (Hinge, Limber, Omada, Sword, and Vori) submitted a combined 44 clinical references, and 9 additional references were identified from manual internet searches. Of these pieces of evidence, 48 articles met the inclusion criteria and were analyzed for findings on the primary outcomes of pain and function, along with secondary outcomes (workplace productivity, mental health, and overall healthcare resource utilization), user experience, and health equity. As described in the ICER-PHTI Assessment Framework for Digital Health Technologies, the evaluation reviews the solutions' clinical effectiveness to understand how they perform clinically on both primary and secondary endpoints of interest, and how long those benefits persist. It also seeks to clarify which populations stand to benefit the most from using the solutions.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

Economic impact: The economic analysis was modeled based on low back pain, which has the strongest evidence, though findings suggest that virtual MSK solutions can be financially beneficial for a wide range of disorders. The model estimates the number of adults who use in-person PT for low back pain and could be eligible for virtual MSK solutions across commercial, Medicare, and Medicaid plans. The model estimates the eligible users with low back pain, the gross reduction in expected healthcare spending from improved access to PT, and the net impact on spending once the savings are offset by spending on the virtual MSK solutions.

## **Summary of Findings**

Based on PHTI's review of clinical evidence, the virtual MSK solutions assessed in this report deliver clinically meaningful improvements in pain and function compared with usual care (which generally includes physician visits and pain management but not PT) for people with a range of MSK disorders. Across the three categories of solutions evaluated, physical therapist-guided solutions can be an effective alternative to in-person PT and have the potential to reduce healthcare spending. At the right price, app-based exercise therapy solutions may be appropriate for patients with lower-acuity. RTM-augmented PT solutions have high clinical efficacy but increases costs, making it most appropriate for more serious MSK disorders. Virtual solutions can close access gaps, particularly among older and rural populations or individuals who cannot easily get to in-person PT clinics.

#### **Category-Specific Findings**

#### App-based exercise therapy solutions

can improve pain and function compared with no PT, but there is no evidence that they improve functional status comparable to in-person PT, and are therefore unlikely to be an effective substitute. At an affordable price, these may be valuable solutions to provide broad-based virtual care for patients with lower acuity who may experience clinical benefits.

Evidence showed that physical therapist-guided solutions, which include clinician-designed care plans and oversight, improve patients' pain and function more than usual care (without PT) and healing naturally. These virtual solutions perform comparably well to in-person PT across most major indicators and, for some people, work as a reasonable substitute for in-person care. Virtual options may be particularly appealing for people who cannot easily reach in-person PT clinics, because of transportation or mobility limitations or geographic access barriers. In addition to lowering the cost of delivering PT, these solutions may improve adherence and speed up the initiation of therapy, resulting in lower average healthcare spending across the population of people with matched MSK disorders.

 If 25% of in-person PT users with low back pain shifted to these MSK platforms at a price of \$995 per year, it would save an estimated \$4.4 million per 1 million commercially insured individuals. Though the evidence base is limited for **RTM-augmented PT solutions,** this category delivers superior clinical results on pain and functional improvement compared with in-person PT alone. However, even after accounting for the health benefits of improved adherence and earlier initiation of PT, these solutions increase annual healthcare spending because they augment in-person care and the estimated savings from lower utilization do not offset the increased costs of RTM billed on top of existing treatment.

- If 25% of in-person PT users with low back pain shift to these MSK platforms, this could increase spending by \$1.7 million per million commercially insured lives.
- Future evidence should focus on how these platforms perform in full-risk, value-based care arrangements, where they may have a positive budget impact due to stronger clinical outcomes that may lead to surgical avoidance and reduce unnecessary care.

Evidence on healthcare resource use suggests that both **physical therapist—guided and RTM-augmented PT solutions** have the potential to significantly reduce downstream healthcare utilization, such as surgeries, injections, specialty visits, and imaging. These are areas that require further economic evidence development, particularly in support of growing purchaser interest in value-based contracting.

Introduction	Technology Context	Clinical Effectiveness	Economic Impact	Summary Ratings	Next Steps
PHTI CATEGO	ORY-LEVEL RATINGS FOR VIR	FUAL MSK SOLUTION	S		

- Positive
   Moderate
   Negative
- Higher Clinical Evidence Certainty
   O Lower Clinical Evidence Certainty

	Clinical Effectiveness	Economic Impact	Summary Rating <sup>b</sup>
App-Based Exercise Therapy <sup>a</sup> Dario, Kaia	Results: Improves pain but         not function; not substitutable         for in-person PT         Evidence Certainty: Lower	Pricing data not available	Evidence supports broader adoption depending on price, particularly for patients with lower-acuity MSK conditions
Physical Therapist–Guided Solutions <sup>a</sup> Hinge, Omada, RecoveryOne, Sword, Vori	Results: Improves both pain and function; comparable to in-person PT Evidence Certainty: Lower	Decreases net spending relative to in-person PT with savings from avoided care	Evidence supports broader adoption
RTM-Augmented PT Solutions <sup>a</sup> Limber	Results: May perform better than in-person PT alone Evidence Certainty: Lower	Increases net spending; savings from avoided care are less than added RTM billing	Ongoing evidence generation needed; may justify broader adoption for patients with higher-acuity MSK conditions

Source: PHTI, Virtual MSK Solutions Assessment, June 2024. See PHTI.org for complete report, methods and recommendations.

Notes: <sup>a</sup> Not all solutions have clinical data that meet the inclusion standards for this report. Based on the similarity of approaches, it is fair to assume that companies without solution-specific data perform in line with the category. Purchasers and users will have to make their own assumptions about performance. <sup>b</sup> Summary rating reflects the combination of clinical and economic results.

## Realizing Full Potential and Next Steps for Stakeholders

While virtual MSK solution companies market themselves on improved access, their current business model and user acquisition strategies are structured as employee wellness benefits that are disconnected from medical benefits and spending. This makes it more difficult for providers and health plans to identify the patients who would benefit the most from these solutions and target them early. Virtual MSK solutions could deliver even better value by integration into the medical benefit, encouragement of earlier referrals to PT, and active management of other avoidable healthcare utilization.

Many of these solutions — especially **physical therapist—guided solutions** — warrant broader adoption and thoughtful contracting to expand their clinical benefits while controlling healthcare spending.

Recommendations include:

 Virtual MSK solutions should be integrated into medical benefits, not wellness programs, to realize the full potential for savings in MSK care;

- Purchasers and providers should encourage more PT-first MSK care;
- Contracts between purchasers and companies should increasingly rely on value-based payment arrangements that build on the economic benefits of these solutions; and
- Solutions should partner with payers and providers to improve patient triage and build evidence for moderate and high complexity MSK care.

These findings are based on the criteria set forth in the ICER-PHTI Assessment Framework and the currently available evidence. Please see the full PHTI report and appendix for complete assessment, methods, and recommendations.

Clinical Effectiveness Economic Impact Summary Ratings

# The Case for Innovation

**People living with musculoskeletal (MSK) disorders suffer from pain and functional limitations.** More than one in three American adults experience MSK problems related to their muscles, bones, joints, or connective tissues, which may result from acute injuries, repetitive motion or strain, or osteoarthritis.<sup>1</sup> These conditions impair patients' daily lives, impact their productivity, limit their ability to work and earn a living, and contribute to high medical spending.<sup>2</sup> As the number of people over age 65 in the United States continues to rise, so too will the demand for MSK services.

## Patients, payers, and providers want to avoid overtreatment and over-

prescription. As the body heals, some patients with MSK conditions will get better over time, regardless of treatment.<sup>3,4,5</sup> For conditions that do not self-resolve, common treatments include pain medication, steroid injections, medical imaging (e.g., X-ray, MRI, ultrasound), and surgery.<sup>6</sup> Researchers have found that many surgeries for MSK conditions are overused and ineffective.7,8,9,10 Additionally, policymakers and physician leaders have called for greater limits on first-line use of prescription opioids<sup>11</sup> and more selective use of medical imaging.<sup>12</sup>

**Early access to PT is critical.** Timely assessment and early use of PT can improve health outcomes and avoid unnecessary spending for MSK disorders.<sup>13</sup> Clinical practice guidelines now often recommend high-quality, nonsurgical MSK care like physical therapy (PT) for many MSK conditions, prior to deciding to undergo surgery.<sup>14</sup> For instance, timely PT can accelerate improvement of acute MSK disorders, such as low back pain.<sup>15,16,17</sup>

#### Access to timely, high-quality, and consistent MSK care can be challenging and costly for patients.

In-person PT is a cornerstone of MSK care. However, many people who would benefit from PT do not pursue it because they perceive that it is too expensive, inconvenient, or inaccessible. One survey found that nearly half of people suffering from MSK pain indicated that in-person PT was too expensive to pursue.<sup>18</sup> Other people live in areas with limited access to convenient in-person PT<sup>19</sup> or face transportation, mobility, or schedule challenges that make it difficult for them to get to in-person PT.

Virtual MSK solutions can improve access, adherence, and outcomes for patients. A range of virtual MSK solutions have come to market, and purchasers — including health plans, employers, and providers — have widely adopted them. If virtual MSK solutions can deliver the same clinical benefits as in-person PT at the time and place a patient chooses, then they have the potential to expand access and improve adherence. This has the potential to improve patients' health and avoid high-cost interventions like imaging, medication, and surgery.

Different MSK solution types address a range of patient needs. People who seek MSK care have a range of needs and goals, from recovering from a mild athletic injury to addressing chronic pain and significant functional limitations. This report reviews the performance of three categories of virtual MSK solutions (eight solutions in total) that share a common goal of delivering virtual MSK care to patients. These solutions vary in how they combine human involvement, automated software, and hardware.

The report incorporates scientific evidence, company data, and budget modeling to answer three fundamental questions: **How well do these virtual MSK solutions work? For whom do they work? Are they worth it?** 

## COMPANIES WITH VIRTUAL MSK SOLUTIONS REVIEWED IN THIS REPORT DarioHealth Hinge Health Kaia Health Limber Health Omada Health RecoveryOne Sword Health Vori Health

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Clinical Effectiveness Economic Impact

# **Technology Context**

Diverse conditions that impact the muscles, bones, joints, and connective tissues are collectively called MSK disorders. These disorders can result in pain and limitations in function, which, in turn can negatively impact productivity and mental health. The MSK category, which affects more than one in three people in the United States,<sup>20</sup> covers a wide variety of conditions and encompasses nearly 10% of medical spending nationally.<sup>21</sup>

The National Academies of Medicine groups MSK disorders into three categories — disorders of the back (e.g., chronic low back pain), osteoarthritis (e.g., issues related to the hip, knee, wrist, and hand), and arthropathies (e.g., rheumatoid and psoriatic arthritis).<sup>22</sup>

MSK disorders vary greatly in intensity, duration, and acuity. Some disorders, such as a broken leg, become apparent after an acute injury in which the cause and time of incident is clear. Other disorders come to attention gradually as the patient notices a difference in their ability to carry out certain activities. Either type of onset can progress to a chronic disorder with long-term persistent pain and functional challenges, which may flare up episodically.

Patients' goals and clinical needs vary considerably. One study of six million patients younger than 65 who had commercial insurance found that two-thirds of patient MSK care usage and costs was attributed to "wear and tear," which includes "strains, sprains, and tears of muscles, tendons, and ligaments; ruptured discs in the spine; and degenerative changes of the joints."<sup>24</sup> While the numbers will vary by population, this large group contained a spectrum of patients, including those with low-severity issues likely to improve with movement, medium-severity issues that may persist or worsen without intervention, and high-severity issues that must be addressed with medical or surgical intervention.

MSK disorders are the leading cause of disability.<sup>25</sup> Employers are particularly concerned about MSK disorders among employees because they can negatively impact productivity and increase healthcare spending. In 2015, U.S. workers lost an estimated 264 million work days from neck and back pain, resulting in \$131 billion in lost earnings.<sup>26</sup> These conditions disproportionately affect certain industries, especially those with high rates of manual labor, such as retail trade, manufacturing, and healthcare and social assistance, which collectively accounted for 50% of private-sector, workplace-related MSK cases in 2018.27

Patients living with or experiencing MSK disorders are at increased risk of mental health challenges, including depression, anxiety, fatigue, and sleep disruption.<sup>28</sup> Further, chronic pain due to MSK disorders can lead to illicit and prescription substance abuse.<sup>29</sup> As the U.S. population ages,<sup>30</sup> the incidence of MSK disorders is projected to continue to increase.<sup>31</sup>

#### Exhibit 2

PERCENTAGE OF MSK-RELATED HEALTHCARE SPENDING BY DISORDER TYPE, 2020<sup>23</sup>



Note. The MSK conditions reflected in this graphic do not include injuries caused by trauma or autoimmune or rheumatological diseases. Source: Evernorth Research Institute. "Americans in Motion." August 2022. <u>https://d17f9hu9hnb3ar.cloudfront.net/</u> <u>s3fs-public/2022-08/Evernorth%20Americans%20in%20</u> <u>Motion%20Musculoskeletal%20Report\_0.pdf</u>

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

### Standard of Care for MSK Disorders

This report focuses on routine MSK disorders, such as those that arise from acute injuries, repetitive motion or strain, or osteoarthritis. While this category may include mild fractures (e.g., hairline fractures), it does not include significant trauma or MSK disorders due to autoimmune disorders, cancers, or infections. The report does not focus on patients during the peri- and postsurgical period (e.g., post-knee or hip replacement) or patients with primary neurological disorders (e.g., stroke, Parkinson's).

While MSK disorders include a wide range of conditions and the standard of care varies, many patients experience a similar treatment journey. Patients often notice sudden or gradual pain or movement limitation in completing daily activities and seek care from a healthcare provider, often their primary care doctor. Providers assess pain, function, and disability, and they may inquire about the patient's quality of life and mental health status. From there, many providers pursue one of three treatment options: a care plan that focuses on pain reduction and includes medication, a referral for imaging (e.g., MRI), or specialist care (e.g., pain or orthopedic specialist). In a usual care

## **Common Problems with MSK Disorder Treatment**

Common problems with MSK disorder treatment include the **overuse of imaging, surgery, and opioids and other pharmacological agents.** Patients undergo imaging across a variety of MSK disorders, though the routine use of imaging is discouraged because it is costly and, in some cases, lacks a strong association with symptoms.<sup>32</sup> There has been an increase in surgeries across MSK disorders, with surgical outcomes comparable to those of less severe interventions such as PT.<sup>33</sup> The efficacy of opioids for MSK-related pain is not backed by strong evidence and has at times been associated with poorer outcomes than PT.<sup>34</sup> Further, patients with MSK disorders are not offered PT as a first option as often or early as they should be.<sup>35</sup>

scenario, PT is not the norm; most people are not offered PT first. Therefore, improving the initial point of evaluation is important to increase the quality of patient care and efficient use of healthcare resources.

Clinical practice guidelines recommend approaches that seek to delay or avoid the need for radiological imaging, pharmacological interventions, and surgery.<sup>36</sup> For example, the Veterans Administration and Defense Department recommend that after screening for serious conditions like malignancy, fracture, or infection, first-line treatments for back pain should focus on nonpharmacologic and noninterventional approaches, such as self-guided exercises or PT.<sup>37</sup> The American Association of Family Practice (AAFP) recommends a similar pathway for treating low back pain, as does the AAFP/American Academy of Orthopedic Surgeons treatment guidelines for knee osteoarthritis.<sup>38,39</sup>

The key "active ingredient" in many of these first-line approaches is an exercise-based or PT regimen. In fact, most states now permit some level of "direct access" to PT,<sup>40</sup> in which a physician referral is not required to access some or all services. Supervised PT, either via referral or direct access,<sup>41</sup> is a core component of these treatment pathways and is frequently used to guide further referrals, interventions, or therapies.

## **L** Treating musculoskeletal disorders can often be challenging...

For example, posterior leg pain can be caused by a pinched nerve in the back, a hamstring injury in the thigh or a baker's cyst in the knee. As such, the treatment plan may need to focus on the spine, the hip or the knee. On the other hand, many minor injuries will get better without any treatment but early participation in rehabilitation exercises will get people back to exercise sooner with less risk of reinjury. Balancing these two facts while being mindful of costs is essential."

— Dr. Adam Bennett

Clinical Assistant Professor of Family and Community Medicine and Orthopedic Surgery, Northwestern University Feinberg School of Medicine Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

Early assessment and PT can improve the health and economic impacts of MSK disorders.<sup>46</sup> Recent research has found that patients with MSK pain managed by physical therapists rather than medical providers have better outcomes, lower costs, and higher patient satisfaction.<sup>47</sup> Additionally, research from the U.S. military found that patients whose first point of care is a physical therapist had reduced healthcare utilization costs, lower rates of referral to specialty care, and decreased rates of long-term disability.<sup>48</sup> Further research found that for some MSK conditions, patients who saw a physical therapist first had a lower probability of having unnecessary imaging services, opioid prescriptions, and emergency department visits. These patients also had lower out-ofpocket costs, as costs were shifted from outpatient and pharmacy to provider settings.<sup>49</sup>

Compared with injections or surgery, PT tends to reduce overall healthcare costs when used as a first-line intervention.<sup>50</sup> For example, beginning a care pathway with a PT appointment instead of an MRI meaningfully decreases healthcare utilization, as does early adherence to a PT treatment plan.<sup>51,52,53,54</sup> In essence, if PT resolves the issue, there is no need to utilize more costly diagnostics or interventions; if it does not, there is a clear rationale for stepping up care.<sup>55</sup> As such, eliminating barriers to PT and identifying solutions that promote adherence to PT should be a goal of healthcare purchasers and the system at large.

#### Exhibit 3 COMMON PATIENT CARE JOURNEY FOR MSK DISORDERS



## **Physical Therapists**

Most licensed physical therapists complete a doctoral degree (DPT) in addition to a bachelor's degree and earn about \$100,000 per year.<sup>42</sup> During PT sessions, they are often supported by physical therapy assistants (PTA) and/or physical therapy aides, or technicians who work under the supervision of a physical therapist. Organizationally, the physical therapist may initiate and maintain the care plan, but some of the care plan may be overseen by an assistant to improve the efficiency of the practice.

The role of physical therapists as first-line providers is growing, as is the demand for PT. As the U.S. population ages and the prevalence of chronic conditions increases, the demand for and employment of physical therapists is projected to grow.<sup>43</sup> A 2022 survey by the American Physical Therapy Association found that outpatient PT clinics had a 17% vacancy rate for physical therapists.<sup>44</sup> These vacancies particularly impact patients in rural areas, where, as of 2021, there were 50% fewer physical therapists per resident than in urban areas.<sup>45</sup> Overall, the current and projected demand for PT exceeds the supply, creating a market opportunity for solutions that can leverage technology to increase the supply of PT.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

#### **Barriers to In-Person PT**

In addition to cost, there are two important barriers to in-person PT: access limitations and restrictions on patients' time.

Access and Availability: Post-COVID workforce shortages have exacerbated patient wait times for PT. Several large national chains offer convenient access in urban and suburban settings; however, patient wait times are higher in rural areas and places with higher costs of living.<sup>56</sup> Additionally, getting to and from in-person PT visits can be a challenge for patients with MSK disorders, especially for people with disabilities or mobility limitations and those who rely on public transportation. One study found that offering a no-cost transportation option increased PT attendance.57

**Time:** In-person PT is time-intensive by nature. For most patients, PT is administered in person by a licensed physical therapist at an outpatient facility. It frequently requires multiple in-person visits per week, and many patients are also encouraged to complete exercises at home between sessions. Some patients struggle to carve out time from work, school, and home responsibilities to attend in-person PT during the facility's operating hours.

Together, these nonfinancial barriers reduce appointment attendance and prevent some people from starting PT in the first place. Virtual PT solutions could address these barriers by extending access to treatment using digital systems that are available from any location and at whatever time the patient prefers to do their PT.

## **Direct Access to PT**

Timely access to PT can help improve patient outcomes and reduce costs. Most states have eliminated restrictions tied to accessing treatment from physical therapists without a prescription or referral, though restrictions around type of treatment (e.g., injury prevention, wellness) and length of treatment (e.g., maximum 30 days, 10 consults) still exist.<sup>58</sup> Of particular note, in January 2024, the Department of Defense (DOD) announced that it will allow physical therapists to act as primary MSK providers across all DOD settings.<sup>59</sup> An 18-month retrospective subgroup analysis of ankle-injury patients found that direct access reduced imaging, referrals to specialty care, long-term disability, visits, and costs.<sup>60</sup> Increasing direct access to PT — both through simplified access to in-person and virtual solutions — may help to address the demand for PT services.

Economic Impact

# Patient Perspective

## **Convenient Access to Care**

Patients appreciate the convenience of virtual MSK solutions that eliminate the need to travel to a PT clinic multiple times per week. Some patients reported challenges getting to and from in-person visits because of therapy-related exhaustion, lack of access to reliable transportation, and mobility issues.

# I really see the benefits of [virtual MSK care]...

rather than driving 30–40 minutes in the traffic. Sometimes I do not feel good, or I just have to ask another person to drive me. I really like the benefits of it and doing it from the comfort of my home."

- Patient Focus Group Participant

### Digital Solutions Cannot Replace In-Person PT for All Patients

While patients generally reported a high level of comfort and satisfaction with the online platforms and quickly adapted to the virtual sessions, they did not necessarily see virtual MSK care as a direct substitute for in-person PT. For example, some patients highlighted the value of manual manipulation and therapeutic ultrasound provided at in-person PT sessions.

## **44** I would not see it as a replacement ...

because there are a lot of hands-on components to PT, which we cannot do through virtual. On top of the exercises, there is also the stretching, massage, TENS [transcutaneous electrical nerve stimulation], or heat and ice. You could do the heat and ice at home, but for the stretching and the other stuff, that is different."

- Patient Focus Group Participant

## **Specialized Services**

Patients value the improved access to specialized care offered by virtual MSK solutions.

## **44** All of my conditions are pretty rare.

I cannot find any doctor that has even heard of it, except for this one [physical therapist] who lives an hour away. This [virtual PT] was the only way to make this possible, and she has so much insight and had so many connections to other types of therapy, too, that it has been incredibly helpful. I am really grateful that that was an option."

- Patient Focus Group Participant

## **Coordination with Other Medical Providers**

Care coordination between virtual physical therapists and other providers was another challenge for patients. While patients were generally satisfied with the care provided by the virtual PT platform, they consistently reported frustration about the lack of care coordination between the virtual platforms and their other healthcare providers.

## **44** My pain specialist...

I have to get printouts to take to him or sign my record over repeatedly, so that he gets the information that helps him."

- Patient Focus Group Participant

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Introduction
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Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

#### Virtual MSK Solutions

Given the scale of the health and economic challenges posed by MSK disorders, virtual PT solutions have attracted significant private investment. Technological innovation in this space has focused on virtual solutions designed to expand access to therapies that reduce pain and improve function. The virtual MSK solutions use computer vision and on-body sensors at home, live and prerecorded digital interactions with therapists, and artificial intelligence (AI)-powered analysis of patient data and care plans. These solutions are

purchased by employers aiming to reduce workforce impacts of MSK disorders and payers who want to increase early access to therapies that can mitigate future health consequences.



Introduction Technology Clinical Economic Context Effectiveness Impact	Summary	Next
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#### Exhibit 5

#### CORE COMPONENTS OF VIRTUAL MSK SOLUTIONS

	App-Base Therapy	d Exercise Solutions	e Physical Therapist-Guided Solutions		RTM-Augmented PT Solutions			
	Dario	Kaia	Hinge	Omada	Recovery One	Sword	Vori	Limber
EXERCISE TRACKING								
Wearable sensor						•		
Computer vision		•	•	•	•	•	•	
PATIENT DATA REVIEW				`				•
Physical therapist				•		•		•
Al/Algorithm	•	•						
CLINICAL STAFF INVOLVED				• •				•
Physical therapist		•	•	•		•		•
Coach	•	•			•			•
Multidisciplinary care team with physician							•	
SOLUTION FEATURES								
Surgical prevention teams*						•		
Referrals to in-person providers		•	•	•	•	•	•	•
Able to write prescriptions								

Notes. \* May include physician consultation.

Public information (websites, marketing materials, company-provided public information, etc.)

The solutions included in this assessment were identified through a multistep market analysis. Products were initially identified through a scan of the virtual MSK management solution space using multiple market analysis platforms and published literature. A company-by-company analysis examined eligible products and grouped those with similar characteristics, claims, customers, and mechanisms of action. The final list of solutions was informed by the results of company meetings, company-submitted data, detailed company research, and input from stakeholders, including health plans, employers, providers, and virtual health experts. All of the solutions included in this report:

- Provide customized patient-specific virtual PT-based care plans;
- Use computer vision, wearable sensors, or human review to provide active oversight of patient adherence to recommended exercises;
- Have received more than \$10 million in funding;
- Seek to replace or augment traditional PT by providing virtual PT between in-person care sessions;
- Sell primarily to health plans, providers, and/or employers; and
- Have clinical pathways/protocols for multiple MSK conditions.

The virtual MSK solutions in this report were created between 5–15 years ago, and the companies represented are among the most mature health technology companies in the U.S. market. Each of the companies that met the inclusion criteria for this report has raised between \$10 million and \$1 billion in capital, with a mix of private and public ownership (see Exhibit 6).

Most virtual MSK solutions aim to provide scaled access to high-quality PT at a lower cost than traditional MSK care. Thus, the solutions substitute automation and technology for skilled labor throughout the patient user

Technology Context

Clinical Effectiveness Economic Impact Summary Ratings Next Steps

## Medical vs. Wellness Benefit

One core difference between virtual MSK solutions is their contracting approach. Many companies described in this report contract with employers and health plans primarily through the wellness benefit. Wellness programs cover a range of services intended to promote healthy living, such as gym memberships, smoking cessation programs, weight management programs, and other benefits. Contracting through the wellness benefit can offer greater flexibility for employers and may result in lower out-of-pocket costs for users. However, it also separates these services from the core medical benefit design and claims processing system, which may limit integration with medical care teams and make it hard to execute outcomes-based contracts.

journey. One company included in this assessment offers a solution to augment in-person PT by providing virtual care between in-person visits. Key factors that distinguish between the solutions include when, how, what type, and under what circumstances live human interactions occur. For instance, solutions vary in initial patient assessments (in-person, virtual, questionnaire, etc.), oversight of therapeutic programs, integration of physician and/or coaching visits, real-time exercise feedback (whether and how it is given), and company physicians' ability to prescribe medications and referrals. Ultimately, virtual MSK solutions aim to improve patients' pain and functional status. They may also produce additional benefits, such as improved mental health or reduced healthcare costs.

#### Exhibit 6

#### **COMPANY HISTORY AND FUNDING**

Company	Year Founded	Ownership	Total Private Investment
Dario	2011	Public	\$238M
Hinge	2014	Private	\$828M
Kaia	2016	Private	\$127M
Limber	2019	Private	\$14M
Omada	2011	Private	\$530M
RecoveryOne	2014	Private	\$55M
Sword	2014	Private	\$325M
Vori	2020	Private	\$56M

Source: Pitchbook Data, Inc.

## Investment in Virtual MSK Solutions Has Been Significant

Since 2010, more than \$4.2 billion of venture capital has been invested in companies in the MSK space,<sup>61</sup> and the value of transactions in the space (including mergers, acquisitions, and other investments) has totaled \$38.2 billion.<sup>62</sup>

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

Exhibit 7

HOW VIRTUAL MSK SOLUTIONS WORK



Technology Context Clinical Effectiveness Economic Impact Summary Ratings

Next Steps

## **Tracking Exercise Completion and Adherence**

**Computer Vision:** Al-powered software uses the camera on a device to observe or "see" the patient and other visual inputs in the image. During a virtual PT session, a patient's movements are analyzed for accuracy, and the software provides real-time feedback on necessary changes to body position and range of motion to complete the movements. Data on range of motion and adherence to the exercise plan are collected and used for movement and progress analysis, either by an algorithm or a human. Data may be used to inform treatment plan modification in addition to measuring exercise performance and adherence.

**Wearable Sensors:** Motion sensors attached to the body via straps track the movement of the body and relay the data collected for further analysis. The data collected are used for dynamic motion analysis and report range of motion and adherence to the exercise plan, such as the number of repetitions or sets completed. The technology used in body movement tracking by wearable sensors does not necessitate AI, but the analysis of the tracked movements to provide feedback on necessary changes to body position may utilize AI.

Algorithm/Al Recommendations: Functional mobility data are collected during exercise sessions, along with patient-reported outcome measures (e.g., pain levels) via surveys. Based on patient progress, an overseeing clinician or an algorithm/Al technology may make changes to the care plan.

As Exhibit 8 shows, the solutions included in this report fall into three categories:

#### App-based exercise therapy solutions

provide self-directed exercise therapy using care plans that are primarily designed and updated by algorithms, based on data from computer vision analysis or on-body motion sensors. In these solutions, there is limited physical therapist involvement once an exercise program is established.

#### Physical therapist-guided solutions

offer virtual PT with a higher level of clinical involvement when onboarding participants, designing exercise therapy regimens, and managing their care. These offerings generally include self-directed exercise programs with feedback from computer vision and/ or on-body sensors. They also offer more frequent human interaction with coaches and physical therapists through both video visits and asynchronous communication.

#### **RTM-augmented PT solutions**

supplement in-person PT with virtual care. These solutions support patients with self-directed exercises between in-person sessions and enable physical therapists to monitor their patient's progress remotely. The primary in-person physical therapist continues to direct care and may bill for the use of these solutions via RTM billing codes.

## Exhibit 8 CATEGORIES OF VIRTUAL MSK SOLUTIONS



Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

The analysis focuses on the ability of virtual MSK solutions to demonstrate under what conditions they are comparable to or "as good as" in-person PT to establish a minimum threshold for clinical effectiveness. This approach assumes that the value proposition is replacement of in-person PT visits with a more convenient and accessible virtual option. The report also assesses clinical outcomes of virtual MSK solutions for people who would not otherwise seek in-person care. Virtual MSK solutions will not be appropriate for all patients. For instance, patients with more complex MSK disorders, those who require manual manipulation or other hands-on therapy treatments, and those who have high frailty or fall risk may still require inperson physical therapy or clinical care.

## **FDA Regulation**

The United States Food and Drug Administration (FDA) regulates some types of computer vision and wearable sensors that offer patient feedback to ensure they produce accurate, reliable measures. The FDA can exercise enforcement discretion on these types of devices if and when the agency determines there is a high risk to patient safety. For some companies included in this report, they assert parts of their solutions are FDA-registered or FDA listed. This label should not be misconstrued as pre-market approval; it conveys they have listed their devices and their places of production with the FDA.

## **Privacy and Security**

Payers and providers continue to emphasize the critical importance of privacy and security when making digital health purchasing decisions. When considering the security risks of virtual MSK solutions, purchasers should pay attention to connection points between their IT systems and those of the digital solutions. Most MSK solutions work with purchasers to access qualified lists of patients or employees. These lists may or may not be identified using personal health information and/or claims filed for a relevant MSK diagnosis code. Once patients are using these platforms, they may be unaware of what information — especially visual information or recordings — may be stored or reviewed by the solution. Even if a platform does not actively record sessions, their user agreements may enable them to do so at a future date. Clinical Effectiveness Economic Impact Summary Ratings

# **Clinical Effectiveness**

Evaluating the clinical performance of digital health technologies for MSK conditions requires a comprehensive understanding of the outcomes that drive results. Using the methods described in the <u>ICER-PHTI Assessment Framework</u>, the systematic literature review included published and unpublished research citations on clinical effectiveness. Most of the citations identified for in-depth review were published in the past three years, but only a few of these included comparator groups and many showed a high risk of bias.

The studies included in our systematic literature review show that researchers and companies have focused on pain reduction and improvement in physical function as the primary clinical outcomes of interest for patients with MSK disorders. Secondary measures, like mental health improvements and decreases in medication and healthcare utilization, are important points to consider within the broader context. In total, the evidence from the literature review leads us to conclude that digital health technologies for MSK care, built on a foundation of virtual PT, are generally comparable to in-person PT in terms of clinical effectiveness and can be useful in extending access to patients who are traditionally underserved or who face barriers to access. However, there are likely limits to the level of patient complexity that virtual MSK platforms can handle without physical interaction with patients.

Additional research, including highquality studies that limit the risk of bias, are needed to demonstrate whether the new technology-enabled approaches can be superior to in-person therapy in specific contexts or if there are areas where in-person therapy is superior to virtual solutions.

## Systematic Literature Review

The systematic literature review for the clinical assessment relied on three main data sources (see Exhibit 9) and the process of identifying, screening, and including citations from these data sources is shown in Exhibit 10.

**4** Patients who seek and participate in physical therapy have various outcomes but the majority of patients would state they benefited in some way. The treatment plan for each patient, however, can vary widely. For example, treating a patient with a complex history, or someone who has had multiple surgeries, requires a more complex plan and ongoing monitoring to improve that patient's outcomes. That is why reducing barriers, particularly financial ones, to high-quality physical therapist guided care is so important."

— Dahlia Fahmy, Physical Therapist



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Exhibit 10

#### PRISMA DIAGRAM OF CLINICAL EFFECTIVENESS STUDIES



Based on the ICER-PHTI Assessment Framework, independent reviewers conducted a systematic literature review of published scientific literature and gray literature on digital health technologies for MSK disorders, in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.<sup>63</sup> The reviewers searched online databases (MEDLINE and EMBASE) and conference proceedings for records based on the predefined inclusion/exclusion criteria described in PHTI's listing in the <u>Prospero Registry</u>. Reviewers screened a total of 2,209 records (i.e., citations) for inclusion. Using the population, intervention, comparators, outcomes, timing, and setting/study design (PICOTS) criteria (see Exhibit 11), reviewers narrowed the records to 43 eligible citations.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

#### Exhibit 11

#### PICOTS INCLUSION AND EXCLUSION CRITERIA

CRITERIA		ON CRITERIA	EXCLUSION CRITERIA
POPULATION	Adults living with MSK conditio low back, knee, hip, shoulder, c	ons or disorders, specifically or neck pain.	<ul> <li>Pediatric population</li> <li>Adults living with any other MSK conditions or disorders or non-MSK conditions or disorders</li> <li>Post/peri-surgical or -operative patients</li> </ul>
INTERVENTION(S)	Virtually enabled PT with/without Dario   Hinge   Ka RecoveryOne	Al that is part of an active care plan aia   Limber   Omada   Sword   Vori	Virtually enabled PT without a real-time feedback loop and that is not part of an active care plan
COMPARATOR(S)	In-person PT     Standard of care	Jsual care No PT	N/A
OUTCOMES	<ul> <li>Physical function</li> <li>Pain (self-reported)</li> <li>Condition-specific pain measures</li> <li>Disability (e.g., Oswestry disability index)</li> <li>Anxiety and/or depression</li> <li>Safety of digital health technology</li> <li>Work productivity and activity impairment</li> <li>Physical activity</li> <li>Head activity</li> <li>H</li></ul>	Jser experience – Engagement level – Patient satisfaction Adherence or program completion Digital health technology-driven shifts in care delivery Healthcare resource utilization office visit, emergency department visit, surgery) Prescription medication use (e.g., opioi Caregiver burden Health equity – Accessibility – Access and distribution	N/A ds)
STUDY DESIGN	Randomized     controlled trials     observa     studies	etional • Systematic reviews and meta-analyses	<ul> <li>Commentary, opinion, study protocols</li> <li>Non-systematic and narrative reviews</li> <li>Case reports or series</li> </ul>
GEOGRAPHY	Global		Interventions not approved or available in the United States
DATA SOURCES	Databases:ConfeMEDLINE (via PubMed)ACSMand EMBASEand AC	rences:Grey literature:I AnnualCompany websiteCRM Annualand U.S. FDA website	N/A
DATE OF PUBLICATION	Databases:         Confer           2013–2023         2021–	<b>ences:</b> 2023	N/A
LANGUAGE	English		N/A

Notes. MSK = musculoskeletal; PT = Physical Therapy; AI = Artificial Intelligence; N/A = Not Applicable.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

Separately, reviewers screened citations that were either submitted by the companies or identified on their websites. Five companies (Hinge, Limber, Omada, Sword, and Vori) of the eight under review provided data in response to PHTI's request for information, from which 44 citations were identified. Manual searches of websites identified an additional nine citations. After screening these 53 citations using the PICOTS criteria, five were included in the systematic literature review, bringing the total number of citations included in the evaluation to 48 (listed in Appendix B-1; see Appendix B-2 for a list of all company-specific citations that did not meet inclusion criteria and reasons for exclusion). All 48 citations were assessed for risk of bias based on quality of design, methods, and analyses (see Appendix A for detailed methodology).

#### **Review of Evidence**

The 48 citations included in the systematic literature review were based on 10 interventional studies, 27 observational studies, and 11 review articles. The body of literature includes studies that focus on pain of different acuities experienced in various parts of the body, use various outcome measures, and examine different categories of PT, at times in relation to comparator groups that also vary. This heterogeneity means that making broad observations is more appropriate than attempting to draw conclusions about a specific MSK diagnosis.

In Exhibit 12, the studies are arrayed by MSK disorder location (e.g., knee, hip, general) and pain acuity (acute vs. chronic). Of the 48 citations included in the review, 34 included pain as a primary outcome measurement, with general MSK disorders being the most frequently evaluated, followed by low back pain specifically.

Notably, the literature review identified no citations focused on neck pain, despite its importance as a frequent cause of pain and physical function disorder. This assessment focuses on PT as the primary intervention modality; thus, fewer citations on knee and hip pain were included, because these conditions are most often studied in surgical literature. While the body of evidence in this literature review is strongest for back pain and general MSK disorders, the clinical efficacy of the digital solutions examined may extend to other lower complexity categories of MSK disorders. However, it is unclear how generalizable these findings are for different MSK disorders and for more serious conditions that may warrant in-person therapy.



Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next

Steps

## Virtual MSK Solutions and Comparator Interventions

The MSK literature includes a variety of virtual therapy interventions. While most use a mobile application and AI for patient tracking and instruction, the integration of technology, therapeutic workflows, and level (and type) of human interaction are unique to each specific solution. Some interventions provide patients with body-worn sensors that send motion-based telemetry to the cloud for real-time feedback and analysis. Others have apps that use the patient's camera phone/device to track their movements via computer vision for feedback and analysis. Human therapists and other personnel can also deliver live or prerecorded lessons.

This assessment prioritizes studies with comparator arms over single-arm studies to understand the incremental value of digital interventions relative to two comparators: in-person PT and "usual care." In-person PT comparators include citations that explicitly require in-person PT participation for their control group. Studies with usual care comparators include a wide variety of treatment approaches - taking over-the-counter medication, following printed educational materials, applying ice, attending physician visits, or getting no medical treatment at all — but do not include in-person PT as a mandatory component of care. However, it is possible that some participants in the usual care comparator groups may have received some form of in-person PT as part of their care. To understand the unique value of digital interventions relative to in-person PT and to usual care, the assessment of clinical effectiveness prioritizes studies with comparator groups over single-arm studies (see PICOTS analysis in Exhibit 11 above for details on the interventions under evaluation).

## Evidence Requirements and Risk of Bias

During the evaluation, reviewers first confirmed that each citation met the minimum evidentiary requirements based on the level of risk these technologies present to users. According to the ICER-PHTI Assessment Framework, the interventions in this report qualify as Tier 3a because they are professionally directed therapeutic services used in consultation with a medical professional. Although the highest-quality research would be a randomized controlled trial, we consider any evidence meeting the minimum standards for Tier 3. given the limited risks to patients from these interventions.

Evidence quality assessments, or risk of bias ratings, were performed on 36 of the 48 citations (12 conference proceedings were excluded because they contained insufficient information). Citations were assessed for risk of bias using standardized methods with the Cochrane Collaboration Risk of Bias in Randomized Trials Version 2 (RoB2) or the Newcastle-Ottawa Scale (NOS) depending on the study design (see callout box for RoB2 and NOS rating criteria).<sup>64,65</sup> Details on the actual risk of bias ratings/judgments for both scales are provided in detail in **Appendix C.** 

## ICER-PHTI Assessment Framework Tier 3a Evidence Standards

The evidence standards for Tier 3a: Professionally Directed Preventive and Therapeutic Health Management are calibrated based on the function of the solutions in the category and the risk to patients of poor performance.

The minimum evidence requirements are high quality observational or quasiexperimental studies with an appropriate comparator and relevant patient outcomes. Outcomes may include patient-reported outcomes, engagement with the healthcare system, or clinical data.

**The best evidence requirements** are randomized controlled trials (RCT) demonstrating clinical efficacy. Studies may be conducted in a selected population. Surrogate outcomes and short-term follow-up may be acceptable.



# Even though the risk of bias is high, the findings are consistent enough to assess clinical effectiveness and economic impact of the solutions, and provide guidance on next steps.

Risk of bias ratings for the 36 ratable citations are shown in Exhibit 13. Overall, the literature on virtual PT solutions includes many studies with a medium to high risk of bias, which increases the uncertainty of study results and limits the ability to draw strong conclusions. A majority (75%) of the citations were rated as having a high risk of bias. None of the studies were in the lowest risk level. Selective reporting and deviation from the intended intervention were common reasons for high risk ratings, as were issues with selection of the study groups.

## Pain and Function as Primary Health Outcomes

Across all studies, the primary end points of interest were pain reduction and improved physical function. Progress toward those goals is informed by both subjective and objective measures. Researchers have developed multiple scales to objectively assess changes in patients' pain and function during clinical studies. Some scales have been validated for comparability across patients, whereas others are best used by one patient over time to gauge subjective or objective progress. Outcomes considered in this assessment were informed by the <u>International</u> <u>Consortium for Health Outcomes</u> <u>Measurement</u> (ICHOM) MSK patient outcome measure sets.

The 34 citations that included pain as an outcome (see **Appendix D**) used nine different pain scales, and the 22 citations that examined change in physical function

(see **Appendix E**) used 11 different scales or a combination of scales. The choice of scales used in each study depends on several characteristics, including whether the scale is being administered in a research or non-research environment and whether a scale is validated for a specific part of the body.

Interpreting small numerical differences in outcomes using unique scales can be difficult. Thus, a two-pronged approach was used to evaluate the data on pain and function: **(1)** did the change reach statistical significance, and **(2)** did the change meet each scale's respective definition of minimal clinically important difference (MCID) PHTI's clinical advisors informed the interpretation of the results.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

#### **Findings on Pain**

Overall, in the 34 citations that reported pain outcomes, patients experienced statistically significant reductions in pain over time. Similarly, among the 11 citations that examined virtual MSK solutions in relation to a comparator arm of any type (see **Appendix F**), patients who received a digital intervention as well as those who received in-person PT or usual care showed decreases in self-reported pain. In other words, patients receiving virtual PT, in-person PT, and/or usual care generally experienced improvements in pain over time.



Exhibit 14



<sup>a</sup> One citation with comparator groups was excluded for having inconclusive findings due to a small sample size and incomplete reporting of results.

## Pain and Function Measurement and Scales

#### Pain

One of the most common validated scales used to measure pain is the **Numerical Pain Rating Scale** (NPRS), which asks patients to score their pain intensity on a scale of whole numbers from 0 to 10. Reductions of two or more points are defined as meeting the MCID. The **Visual Analog Scale** (VAS) asks patients to mark a spot that corresponds to their pain intensity on a 10 cm line, allowing the clinician to measure the distance in millimeters and create a 100-point scale within which a 30% reduction from baseline is considered the MCID. Another pain rating scale used in the cited studies is the **PROMIS Pain Interference** (PROMIS-PI) scale, in which patients are scored on a five-point scale based on how much their pain interferes with their daily living, and the MCID is defined as a change of two points.

#### Function

Measures of function include the Knee Injury and **Osteoarthritis Outcome Score-Physical Function Shortform** (KOOS-PS), in which patients' responses yield a score of 0-100, and the MCID is defined as a 10-point change; the Oswestry Disability Index (ODI), in which patients' subjective views on how much low back pain inhibits their daily living are translated into a percentage, and a 10-point change is considered the MCID; and the Patient-Reported Outcomes Measurement Information System – Physical Function Scale (PROMIS-PF), which places patients on a 100-point bell curve based on their level of physical function, and for which a change of 2.4 points is the MCID. Other measures include the Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH) Scale, which is designed for arm, shoulder, and hand disabilities, and the Hannover Functional Ability Questionnaire (HFAQ) and Lumbar Computerized Adaptive Test (LCAT) scales for back pain.

To compare studies across these varied scales, this report focuses on whether the MCID is achieved. See **Appendices G** and **I** for details on these scales and their MCID definitions.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

Of the 11 comparative citations on pain, seven compared digital interventions to usual care that did not include in-person PT (labeled in citations as "Treatment as Usual," "Education," "Non-participants," or "No Treatment"). These citations use varying levels of detail in reporting outcomes data (e.g., some report within-group change from baseline with or without p-values, some report the proportion of patients achieving MCID without change from baseline, some report between-group differences in change from baseline, etc.). Overall, these studies show that patients who received virtual PT had greater improvements in pain than patients receiving usual care. This finding suggests that patients without access to in-person therapy would benefit from

virtual access. However, to gauge whether the digital intervention's performance is "as good as" in-person PT, virtual MSK care must be compared directly with in-person PT.

Only four citations compared pain outcomes of patients receiving virtual MSK care with those of patients receiving in-person therapy (see Exhibit 16). These studies examined interventions for the lower back, knee, and shoulder, and included a mix of acute and chronic pain. They included as many as 140 people in each study sample and had 8–12 weeks of follow-up. Three of the studies measured pain using the NPRS; the remaining study used the PROMIS-PI. A description of each scale, its scoring scheme, and MCID thresholds are shown in **Appendix G.**  Considering both statistical significance and MCID, the digital solutions used in the three studies that used NPRS were comparable to in-person therapy in terms of pain reduction. The fourth study, specific to knee pain, used the PROMIS-PI with 50 participants and found that the digital solution had superior results after eight weeks. All four of these interventional studies had a medium to high risk of bias because of concerns over selective reporting of results, deviation from the intended intervention, and biased outcome measures. As shown in Exhibit 16, all four citations found that virtual PT solutions performed comparably to in-person PT, with patients in both groups reporting clinically meaningful reductions in pain over time.

#### Exhibit 15

#### CITATIONS EXAMINING PAIN OUTCOMES FOR DIGITAL SOLUTIONS COMPARED WITH USUAL CARE

Company	Citation (I/O)	MSK Disorder Type	Follow-Up	N	Scale <sup>1</sup>	Risk of Bias	Virtual MSK Performance Relative to Usual Care <sup>2</sup>
		APP-BASED EXER	CISE THERA	PY SOLUTI	ONS		
Kaia	Priebe 2020 (I)	Acute low back pain	12 weeks	941	NPRS	High	Superior
		PHYSICAL THERA	PIST-GUID	ED SOLUTI	ONS		
Hinge	Hong 2022(0)	Acute general MSK pain	12 weeks	171	VAS	Moderate	Superior
Hinge	Mecklenburg 2018 (I)	Chronic knee pain	12 weeks	155	VAS	High	Superior
Hinge	Shebib 2019 (I)	Chronic low back pain	12 weeks	177	VAS	High	Superior
Hinge	Wang 2022a (O)	Acute general MSK pain	12 weeks	937	VAS	High	Superior
Hinge	Wang 2022b (O)	Chronic general MSK pain	1 year	4,370	VAS	High	Superior
Sword	Areias 2022 (O)	Chronic general MSK pain	1 year	867	NPRS	Moderate	Superior

Notes. I = Interventional study; O = Observational study. NPRS = Numeric Pain Rating Scale. VAS = Visual Analog Scale.

<sup>1</sup> If a study used more than one scale, the one more commonly reported among all studies is shown here.

<sup>2</sup> It is possible that some portion of participants in comparator arms described as "treatment as usual" or "standard of care" received some form of in-person PT as part of their care, although this was not explicitly reported in the citations.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

Exhibit 16

#### CITATIONS EXAMINING PAIN OUTCOMES FOR DIGITAL SOLUTIONS COMPARED WITH IN-PERSON PT

Company	Citation (I/O)	MSK Disorder Type	Follow-Up	N	Scale <sup>1</sup>	Risk of Bias	Virtual MSK Performance Relative to In-Person PT
		APP-BASED EX	ERCISE THE	RAPY SOLUTI	ONS		
Kaia	Toelle 2019 (I)	Acute and chronic low back pain	12 weeks	86	NPRS	High	Comparable
		PHYSICAL THE	RAPIST–GU	IDED SOLUTIO	ONS		
Sword	Cui 2023 (I)	Chronic low back pain	8 weeks	140	NPRS	Moderate	Comparable
Sword	Pak 2023 (I)	Chronic shoulder pain	8 weeks	82	NPRS	Moderate	Comparable
		RTM-AUG	MENTED PT	SOLUTIONS			
Limber	Gruner 2021 (I)	Acute and chronic knee pain	8 weeks	50	PROMIS-PI	Moderate	Superior

Notes. I = Interventional study; O = Observational study. NPRS = Numeric Pain Rating Scale; PROMIS-PI = Patient-Reported Outcomes Measurement Information System – Pain Interference scale. <sup>1</sup> If a study used more than one scale, the one more commonly reported among all studies is shown here.

## **Findings on Function**

Overall, the findings from 22 citations show that patients using virtual MSK solutions reported improvement in physical function over time. Among the 12 citations with comparator groups (see Appendix H), patients in virtual PT as well as those in various types of comparator groups showed improvements in function. In other words, patients receiving virtual PT, in-person PT, and/or usual care generally experienced functional improvements over time.

#### Exhibit 17 CITATIONS ON FUNCTION



<sup>a</sup> One citation with comparator groups was excluded for having inconclusive findings due to a small sample size and incomplete reporting of results.

Exhibit 18

#### CITATIONS EXAMINING FUNCTIONAL STATUS FOR DIGITAL SOLUTIONS COMPARED WITH USUAL CARE1

Company	Citation (I/O)	MSK Disorder Type	Follow-Up	N	Scale <sup>1</sup>	Risk of Bias	Virtual MSK Performance Relative to Usual Care <sup>2</sup>
		APP-BASED EXE	RCISE THER	APY SOLUT	IONS		
Kaia	Priebe 2020 (I)	Acute low back pain	12 weeks	941	HFAQ	High	Superior
		PHYSICAL THEF	RAPIST-GUI	DED SOLUT	IONS		
Hinge	Hong 2022(0)	Acute general MSK pain	12 weeks	171	Various <sup>a</sup>	Moderate	Superior
Hinge	Mecklenburg 2018 (I)	Chronic knee pain	12 weeks	162	KOOS-PS	High	Superior
Hinge	Shebib 2019 (I)	Chronic low back pain	12 weeks	177	ODI	High	Superior
Hinge	Wang 2022a (O)	Acute general MSK pain	12 weeks	937	Various <sup>a</sup>	High	Superior
Hinge	Wang 2022b (O)	Chronic general MSK pain	1 year	4,370	Various <sup>a</sup>	High	Comparable
Sword	Areias 2022 (O)	Chronic general MSK pain	1 year	867	Various <sup>b</sup>	Moderate	Superior <sup>c</sup>

Notes. I = Interventional study; O = Observational study. HFAQ = Hannover Functional Ability Questionnaire. KOOS-PS = Knee Injury and Osteoarthritis Outcome Score Physical Function Shortform. ODI = Oswestry Low Back Disability Questionnaire.

<sup>1</sup> If a study used more than one scale, the one more commonly reported among all studies is shown here.

<sup>2</sup> It is possible that some portion of participants in comparator arms described as "treatment as usual" or "standard of care" received some form of in-person PT as part of their care, although this was not explicitly reported in the citations.

<sup>a</sup> Includes multiple scales: RMDQ-11 (11-item Roland Morris Disability Questionnaire: back pain only), KOOS-PS (knee pain only), HOOS-PS (Hip disability and osteoarthritis outcome short form; hip pain only), SPADI (Should Pain and Disability Index; shoulder pain only), sf-NPAD (Neck Pain and Disability Scale short form; neck pain only).

<sup>b</sup> Includes multiple scales: QuickDASH, HOOS-PS, KOOS-PS, ODI, NDI, Quick-FAAM.

° Based on between-group difference result in ITT analysis; no within-group results reported.

#### Exhibit 19

#### CITATIONS EXAMINING FUNCTIONAL STATUS WITH DIGITAL SOLUTIONS COMPARED WITH IN-PERSON PT

Company	Citation (I/O)	MSK Disorder Type	Follow-up	N	Scale <sup>1</sup>	Risk of Bias	Virtual MSK Performance Relative to In-Person PT
		APP-BASED EXE	RCISE THER	APY SOLUTI	ONS		
Kaia	Toelle 2019 (I)	Acute and chronic low back pain	12 weeks	86	HFAQ	High	No improvement in either group
		PHYSICAL THEF	RAPIST-GUI	DED SOLUTI	ONS		
Sword	Cui 2023 (I)	Chronic low back pain	8 weeks	140	ODI	Moderate	Comparable
Sword	Pak 2023 (I)	Chronic shoulder pain	8 weeks	82	QuickDASH	Moderate	Comparable
Other <sup>2</sup>	Werneke 2022 (O)	Acute and chronic low back pain	NR (~1 yr)	2,666	LCAT	Moderate	Comparable
		RTM-AUG	MENTED PT S	SOLUTIONS			
Limber	Gruner 2021 (I)	Acute and chronic knee pain	8 weeks	50	PROMIS-PF	Moderate	Superior

Notes. I = Interventional study; O = Observational study. NR = Not Reported. HFAQ = Hannover Functional Ability Questionnaire. ODI = Oswestry Low Back Disability Questionnaire. Quick-DASH = Quick Disabilities of the Arm, Shoulder and Hand. LCAT = Lumbar Computer Adaptive Test. PROMIS-PF = Patient-Reported Outcomes Measurement Information System – Physical Function scale.

<sup>1</sup> If a study used more than one scale, the one more commonly reported among all studies is shown here.

<sup>2</sup> Study used NetHealth technology to examine asynchronous virtual PT outcomes.

 $\leftarrow$  31  $\rightarrow$ 

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

Seven of the 12 citations on function compared virtual PT with usual care comparators that did not include in-person PT (labeled in citations as "Treatment as Usual," "Education," "Non-participants," or "No Treatment"). As with citations on pain outcomes, these citations provide varying levels of detail in function outcomes data. Similar to the findings on pain, people who used the virtual PT solutions were found to have greater functional improvements than those who received usual care. The superior performance of virtual PT solutions over usual care suggests that patients receiving usual care may benefit from the addition of virtual PT.

Five citations compared function outcomes for patients receiving virtual MSK care with those for patients receiving in-person PT (see Exhibit 19). Four of these studies included 140 or fewer participants who were assessed at an eight- to 12-week follow-up; these are the same four studies that were assessed for pain above. A fifth study included 2,666 participants who were followed for approximately one year.66 The risk of bias of these references was medium to high, primarily due to selective reporting of results, deviation from the intended intervention, and biased outcome measures. Each of these studies used a different measurement tool, as shown in Exhibit 19 (see Appendix I for details on other function scales used by citations included in the literature review).

Four of the five citations found that virtual PT worked at least as well as in-person treatment, and the remaining study found that neither therapy led to results that were clinically significant. Even though four of the five citations were the same as those evaluated for pain outcomes, fewer showed statistically significant improvements in function.

## Primary Outcomes by Category

The findings from the key comparator studies on pain and function (see Appendix J) demonstrate that different categories of solutions have different results. Solutions that rely on app-based feedback and generally do not include a physical therapist in their core process (i.e., app-based exercise therapy solutions) show significant and clinically meaningful improvements in pain but no evidence of improvement in physical function. Conversely, virtual solutions that more fully integrate a physical therapist into the process (physical therapist-guided or RTM-augmented PT solutions) show improvements in both pain and function. RTMaugmented PT solutions (represented in this evaluation by one company, Limber Health) augment in-person PT with a home-based remote therapeutic monitoring service; one small eightweek company study indicates that addition of RTM therapy in addition to in-person PT performs better than inperson therapy alone.<sup>67</sup> In the solutionspecific analysis section, each solution's contribution to pain and functional improvements is analyzed within its respective category.

## Secondary Outcomes

Successful interventions to improve patient pain and function may also lead to secondary benefits, such as increased workplace productivity, improved mental health, and lower overall healthcare resource utilization. **Appendix K** contains detailed tables of findings related to these secondary outcomes.

Overall, the findings for these outcomes are more diffuse and inconsistent than those for the primary health outcomes, particularly given the variance in measurement scales, disorder types, and demographics. The following summaries reflect outcomes of virtual PT solutions across diverse patients and settings; however, the diversity limits the ability to draw strong conclusions.

## Workplace Productivity and Activity Impairment

Pain and functional limitations often affect work productivity and activity impairment (WPAI), and WPAI is a common secondary outcome in the systematic literature review. Changes in WPAI were measured in 12 citations

## **Summary Findings: Pain and Function**

Studies showed that across all three categories of solutions, patients who used virtual MSK tools had greater improvements in pain and function than those who received usual care (no PT). This finding suggests that patients without access to in-person therapy would benefit from virtual access.

Studies generally showed that virtual MSK solutions in the **physical therapist–guided category** performed comparably to in-person PT and delivered clinically-meaningful reductions in pain and function. This finding suggests some patients may be able to substitute virtual MSK solutions for in-person PT.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

(11 from Sword and one from Hinge) via an overall WPAI score and, in some cases, individual subscale scores indicating MSK pain or functional limitation that negatively influenced participants' work, work time, and/or work activity.

The evidence included 11 observational studies and one interventional study across a variety of disorder types and acuities, and including patients from different sociodemographic statuses and rural or urban settings. Ten of the 11 observational studies drew from a single prospective database as the source for their analyses, which is a significant reporting weakness that both overstates the robustness of the evidence and limits its generalizability. Only one study compared WPAI with comparator arms of interest and found no significant differences in WPAI overall or its subscales between patients using virtual PT versus in-person PT: patients in both groups improved over time.

The directional evidence suggests that virtual PT had the same productivity improvements as in-person PT; however, more research is needed to support this conclusion.

#### Mental Health

Prolonged pain, loss of physical function, and/or new onset of disability often contribute to worsening mental health.<sup>68</sup> While improvements in depression and anxiety are associated with reductions in patient-reported pain, it is not clear whether reducing patients' pain results in benefits to their mental health.<sup>69</sup> Mental health outcomes identified in the systematic literature review came from app-based exercise solutions and physical therapist–guided solutions, and included depression (19 citations), anxiety (18), health-related quality of life (7), fear/avoidance of daily activities (9), and stress (1). Many of the studies examined mental health outcomes alongside primary pain and function outcomes to better understand how virtual therapy solutions could improve these aspects of patients' well-being.

Four of the 18 citations on anxiety <sup>70,71,72,73</sup> and three of the 19 citations on depression<sup>74,75,76</sup> included comparator arms with patients receiving other forms of care. Results were mixed and indicate that patients who received virtual therapy solutions experienced similar mental health improvements (decreased depression and anxiety) over time as patients who received other forms of care.

One study measured patients' stress over time and found that those who received virtual PT reported significantly less stress at a three-month follow-up than those who received the standard of care.77 This result came from a single study rated as having a high risk of bias; thus, these between-group differences should be interpreted as inconclusive. Three citations compared health-related quality of life in a virtual therapy care group with the following comparator groups: education and treatment as usual, in-person PT, and standard of care.78,79,80 Both intervention and comparator groups in all three citations showed significant or clinically meaningful improvements over three months. Similarly, three citations found that fear or avoidance of daily activities decreased over time in patients who received virtual therapy and patients who received in-person PT, education plus treatment as usual, or no intervention, with no significant between-group differences over time.<sup>81,82,83</sup>

A recent cohort study of 11,236 adults found that relatively large improvements in pain (via the PROMIS-PI scale) and function (via the PROMIS-PF scale) are required for meaningful improvements in anxiety symptoms.<sup>84</sup> However, in that study, neither improvement in pain nor physical function was associated with improvements in depressive symptoms.

Based on these findings, purchasers of virtual MSK solutions should examine their primary impact on pain and functional improvements. Potential for additional mental health benefits from virtual PT are limited, and additional mental health—focused solutions should be evaluated independently.

#### Healthcare Use and Behavior

When pain and functional limitations persist, patients may be more likely to use more healthcare, including medications. Despite promising signs, the studies reviewed in this evaluation found that virtual MSK solutions showed mixed results in decreasing healthcare resource utilization and medication use.

Healthcare Resource Utilization (HCRU) refers to the use of healthcare services, including invasive and emergency care (i.e., injections, emergency room, and surgery), conservative care (i.e., PT, chiropractor, osteopath), imaging, and prescription drug use. Two of the three citations that reported HCRU outcomes included a nonparticipant comparator arm. The percentage of people who used conservative care at one-year follow-up was significantly smaller for virtual MSK solution groups than for the nonparticipant comparator groups in both studies.<sup>85,86</sup> Also, one of these studies showed a significantly smaller

 $\leftarrow$  33  $\rightarrow$ 

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

## **Measure of Surgical Intent**

Throughout the literature, selfreported "surgical intent" is used as a predictor for future high-cost healthcare utilization. The measure asks patients how likely they are to have surgery in the next 12 months and tracks changes in responses over time. Some companies then estimate healthcare cost savings based on reductions in self-reported surgical intent. However, the measure is not a reliable predictor of future healthcare utilization. When patients first seek care, their pain or functional impairment is often high, and they are therefore likely to report high rates of surgical intent. As time elapses or they receive first-line care, patients' self-reported surgical intent often diminishes significantly. However, there is no clear correlation between a decrease in surgical intent and a decrease in actual surgeries.<sup>89</sup> This assessment does not consider changes in surgical intent as a proxy for decreased healthcare utilization or spending.

percentage of people obtaining invasive and emergency care, as well as imaging services, within the virtual MSK group compared with the nonparticipant group.87 The third citation was a single-arm study that only reported on medication prescriptions at follow-up.<sup>88</sup> These limited study data demonstrate a need for well-designed studies to understand how virtual MSK solutions may impact specific types of HCRU and what services are needed for improved pain and functional outcomes. Additional details on company-submitted HCRU evidence is included in the economic impact section.

**Medication Use** refers to patients taking opioid and analgesic medication, whether prescription or over-the-counter. In an era in which opioid abuse disorder remains a significant public health challenge, these findings merit scrutiny. A total of 13 citations explored medication use outcomes, nine of which were produced by Sword, three by Hinge, and one by Kaia. Six citations examined participants who received virtual MSK solutions relative to a comparator group; however, only three of these reported between-group differences, and only one reported a significant betweengroup difference. In the latter citation, an observational study by Hinge, patients using virtual MSK solutions had slightly

lower analgesic and opioid use than a propensity score-matched group.90 Three citations from Sword based on single-arm study designs reported significant decreases in analgesic use over time, but without a comparator group it is not possible to attribute this change to the digital intervention. The four remaining citations, also from Sword, reported either baseline or follow-up (not both nor change over time) data, leaving gaps in understanding of medication use patterns over time. Taken together, the findings of these studies present potential, but weak, evidence that virtual care programs yield decreases in medication use similar to those of inperson programs.

## **Summary Findings for Secondary Outcomes**

**Workplace Productivity:** Directional evidence suggests that virtual PT resulted in the same productivity improvements as in-person PT, but more research is needed.

**Mental Health:** Results were mixed and indicate that patients who received virtual therapy solutions experienced similar mental health improvements (decreased depression and anxiety) over time as patients who received other forms of care.

Healthcare Utilization: More research is needed to demonstrate how virtual MSK solutions impact healthcare utilization over time.

Medication Usage: Findings broadly suggest that virtual care programs yield similar decreases in medication use as in-person programs.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

#### **User Experience**

A core claim of virtual therapy providers is that their solutions improve patient adherence and engagement and increase access to care. Evidence from the literature review generally supports this notion, with caveats, as discussed.

Many of the 48 citations in the systematic literature review contained measures of user experience (see **Appendix L**). Overall, users of virtual MSK solutions reported completing more sessions per week and having slightly better adherence in the first eight weeks of use than those in comparator groups but, otherwise, they performed similarly. Considering the high satisfaction ratings and low risk of harm described below, the findings support using virtual MSK solutions as replacements for in-person therapy.

Adherence to therapy plans was reported in 25 citations, measured primarily by retention and/or drop-out rates. Singlearm observational studies indicated retention rates of roughly 70–80% at 12 weeks follow-up for virtual MSK solutions. Two comparator studies — one based on a physical therapist-guided solution and one based on an RTM-augmented PT solution — showed comparable retention rates at eight weeks for participants using virtual PT solutions and those receiving in-person PT, although there was greater variability in adherence among virtual group participants.<sup>91,92</sup> One in-person PT comparator study provided adherence data at 12 weeks, showing lower adherence within the app-based exercise therapy solution group compared with the in-person PT group.93 Overall, the evidence on adherence is mixed but generally shows similar adherence between virtual MSK solutions and in-person.

Patient engagement are derived from 27 studies of app-based exercise therapy and physical therapist-guided solutions that reported a number of weekly exercise sessions. The number of comparator studies is sparse, with incomplete reporting of data or biased reporting in that analyses are conducted using per-protocol analyses as opposed to intention-to-treat analyses. Overall, data from the interventional studies with in-person PT comparators indicate that users of virtual MSK solutions had slightly more weekly sessions, on average, than those in comparator groups (mean: digital health technology groups=2.9; comparator groups=2.2).94,95,96

**Patient satisfaction** was high across 18 studies from all three virtual MSK solution categories. Patients receiving virtual MSK therapy reported high user satisfaction, with median scores greater than 8 on a 0–10 scale (range: 8.4–9.3). Participants 44 years of age or older tended to report higher satisfaction than those younger than 44.<sup>97</sup>

**Safety** data were reported in six studies. Adverse events were infrequent, and no serious adverse events were reported. While virtual therapies are broadly considered safe, Tier 3 interventions have the potential for incorrect diagnosis or feedback that results in worsening pain or functioning or delays in care. The data suggest that virtual MSK solutions are safe for use.

#### Health Equity

Although MSK disorders are widespread, they disproportionately affect older and lower income individuals. Workers in service industries frequently engage in intense physical labor and repetitive motions, which place them at a heightened risk for MSK issues. These industries encompass a wide range of work, including commercial and residential cleaning, food services, agricultural labor, and factory work. The people who perform these types of work are disproportionately affected by MSK issues, which can hinder their ability to earn a livelihood.

Evidence on the impact of virtual MSK solutions on health equity was considered in two dimensions, both of which may be related to and/or directly impact the clinical effectiveness of a given solution:

- **Inclusivity:** whether the virtual MSK solution is culturally and linguistically appropriate, has a low barrier to entry for digital literacy, reduces implicit biases, and is adaptable to meet the usability needs of populations more likely to experience health disparities; and
- Access: whether the solution is available/distributed across different patient subpopulations and geographic areas (e.g., rural vs. urban areas, socioeconomically diverse communities).

Across the entire body of evidence, some citations reported on one or more of the following patient characteristics: race/ethnicity (9 citations), geographic location (4 citations), education level (6 citations), and employment (16 citations; see Appendix M for patient characteristics). Overall, the evidence on health equity is sparse, with most insights reliant on one or two studies. Generally, the findings suggest that virtual solutions can increase access to care by providing convenient options, particularly for racially and ethnically diverse populations, older adults, and those who have limited access to in-person therapy. As a result, virtual

 $\leftarrow$  35  $\rightarrow$ 

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

solutions have the potential to improve health outcomes related to MSK disorders in traditionally underserved populations.

Race/ethnicity data were reported in seven studies, but only one citation reported outcomes by racial/ethnic subgroups.98 This citation, which examined the Sword intervention, found that pain reduction (using the NPRS scale) was significantly higher in Black and Hispanic patients than in non-Hispanic white patients, and the proportion of Hispanic patients achieving the MCID threshold was higher than that of non-Hispanic white patients. These findings preliminarily suggest that virtual MSK solutions can effectively improve primary health outcomes for Black and Hispanic patients.

The same citation reported comparable retention rates across most ethnic groups, except for Hispanic patients, who were significantly more likely to end therapy early than non-Hispanic white patients. The average number of sessions was statistically significantly lower among Black and Hispanic patients (2.4 sessions per week) than among non-Hispanic white patients (2.7 sessions per week). However, patient satisfaction rates were high and comparable across racial and ethnic groups, ranging from 8.8 to 9.3 on a 10-point scale. Overall, these findings suggest that patients who engage with virtual MSK solutions as intended are all likely to benefit.

#### Geographic and sociodemographic

data show that retention rates were statistically significantly higher in rural than urban communities (77% vs. 74%), although the weekly number of exercises and user satisfaction were similar in both groups.<sup>99</sup> Notably, pain

reduction in rural and urban communities was also similar. One study from Sword examined health equity in relation to engagement and pain outcomes by screening patients using the Social Deprivation Index, a composite of demographic characteristics including living in poverty; having fewer than 12 years of education; and living in single-parent, rental, and overcrowded households.<sup>100</sup> Although higher social deprivation was associated with greater disease burden at baseline, all participants showed significant improvements in pain, regardless of social deprivation scores. The data showed no significant between-group differences in engagement.

It is important to note that in some studies, participants were offered Wi-Fi hotspots if they lacked home internet access. Internet access is a persistent obstacle for broad access to virtual MSK solutions and should be considered when making decisions to adopt these solutions.

Although only a small number of citations report on these outcomes, the findings are encouraging. They suggest that virtual MSK solutions could close access gaps for rural communities and remain effective when they do so.

**Age** data indicate promise for expanding access to MSK solutions across age groups, particularly for older adults. Most studies in the literature review reported patient ages. Across studies, older patients showed higher retention (83% vs. 67%) and lower dropout rates (15% vs. 32%) than younger patients.<sup>101,102</sup> One citation from Sword found that patients older than 65 performed more exercises per week than younger patients (3.1 vs. 2.5).<sup>103</sup> Similarly, a study by Omada Health found that patients

older than 59 had 78% greater odds of engagement and performed at least 64% more exercise sessions per week than patients in their 20s.<sup>104</sup> A study by Hinge found Gen Xers and working age Baby Boomers had significantly higher odds of starting the program, and that Gen Xers, working age Baby Boomers,<sup>a</sup> and retirees had significantly higher odds of program completion.<sup>105</sup> In terms of primary health outcomes, one study found that the impact of virtual PT on pain was comparable across age groups, <sup>106</sup> supporting the claim that digital technologies for MSK disorders may provide health benefits to participants across the age spectrum.

Although sparse, studies that reported user experience and health equity data contain bright spots that are encouraging

## Summary Findings: User Experience and Health Equity

- Virtual MSK users report completing more sessions per week than those in comparator groups, have high user satisfaction, and report few adverse events.
- Across all users, virtual MSK solutions and in-person PT have similar rates of adherence, meaning that patients are equally likely to complete their recommended treatment regimens.
- Older patients generally show higher retention rates, lower dropout rates, and more exercises completed per week than younger patients.
- Though data on race and ethnicity are limited, virtual MSK solutions show signs of improving primary health outcomes across all racial and ethnic backgrounds.



Technology Context Clinical Effectiveness Economic Impact Summary Ratings

for the wider distribution of virtual MSK solutions. Their findings lend credence to the notion that virtual MSK solutions can increase access by providing a more convenient option, particularly for those whose access to in-person PT may be limited by such factors as transportation, proximity to a provider, or work and family obligations.

## **Solution-Specific Analysis**

In addition to reviewing the study findings broadly, this assessment examined sources that relate to the performance of specific companies' virtual MSK solutions, including conference proceedings (i.e., abstracts and posters), to gain a more complete picture of each of the solutions offered. The solution-specific evaluations include evidence drawn from the literature review, as well as solution-specific information identified via internet search and solution-specific evidence submitted by five companies (Hinge, Limber, Omada, Sword, and Vori).

Not all solutions in this report have clinical data that meet the inclusion standards based on the assessment methodology. Given the similarity of approaches across the assessment categories, this report assumes that companies without solution-specific data are likely to perform in line with the rest of the category. However, purchasers and users will need to make their own assumptions about performance. Some companies may also update their products going forward in ways that impact the results.

## App-Based Exercise Therapy Solutions

Dario and Kaia both offer app-based exercise programs that assign participants to personalized plans using self-reported information and computer-vision fitness tests without human assistance. Both companies report that their exercise programs are designed by physical therapists, but neither includes contact with a licensed physical therapist during patient intake and program selection. Both solutions provide real-time exercise feedback via computer vision (Dario also uses a sensor, whereas Kaia does not) and health coaching. Notably, Kaia's automated intake process identifies high-risk patients and may triage these patients to telemedicine appointments with medical professionals.

**Dario:** The company-specific review did not identify any relevant references on Dario's MSK solution, nor did Dario supply information for this evaluation. Dario offers a digital-first exercise program and posture training solution (Dario acquired UpRight Technologies, a posture training sensor, in 2021.) While no clinical evidence was identified for the Dario exercise solution, UpRight has three posture-related studies, which were excluded from analysis as they do not focus on Dario's core exercise program offering (see **Appendix B-2**).

**Kaia:** Kaia did not submit information for this assessment. A company-specific evidence review identified six references for Kaia, two of which met inclusion criteria. Both included studies had a high risk of bias, were 12 weeks in duration, focused on back pain, and were performed in Germany. Both included comparator arms: one of education plus PT and the other of "standard care," which was defined as adhering to German guidelines for the treatment of lower back pain. The study that compared the Kaia app to standard care showed significant improvements that met the MCID threshold for pain (NPRS) for the digital intervention group but not the control group.<sup>107</sup> This study also demonstrated a small functional improvement for the digital intervention group relative to the control group, but MCID was not reported. The second study demonstrated significant pain reduction that met the MCID threshold for both the digital intervention group and the control group (in-person PT plus education).<sup>108</sup> This study did not demonstrate improved functional outcomes for the Kaia participants or the in-person PT users. Of note, recent changes on Kaia's website suggest the addition of new options for patients to engage directly with physical therapists via the Kaia app. However, all included studies in this assessment were conducted using earlier versions of the Kaia solution.

## Summary Findings: App-Based Exercise Therapy Solutions

- The literature on **app-based exercise therapy solutions** is limited to only a few studies, each having a high risk of bias.
- This literature suggests that **app-based exercise therapy solutions** improve pain and functional outcomes compared with usual care.
- However, there is insufficient evidence that these solutions are effective substitutes for in-person PT, as they have demonstrated improvements in only pain, not function.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings

The four excluded studies were all identified through a search of Kaia's website and did not meet the inclusion criteria. Two studies focused on outcomes outside the scope of the evaluation (sleep, app user-interface changes). One study was a postmarket analysis of adverse events, and one was a single-arm study of a preselected population of app users that demonstrated improvements in pain.

## Physical Therapist–Guided Solutions

The physical therapist-guided solutions consist of solutions that combine virtual interactions with physical therapists and other care providers with at-home exercise programs. These solutions provide patient care plans designed and overseen by humans (physical therapists, physicians, coaches, or a combination). Real-time PT guidance and adherence tracking are primarily provided by AI computer vision, although some solutions have the option of live oversight. Solutions in this category assign a physical therapist (or other provider) to each participant to oversee and modify their care plan and provide ad hoc guidance and communication via asynchronous communication and virtual appointments. For example, Omada matches patients with a dedicated licensed physical therapist for the course of their treatment. The ratio of licensed physical therapists to users varies significantly within the category. In addition to providing access to a physical therapist, most solutions include a care team that supports behavior modification through a health coach (and may include other providers). The exception to this is Sword, which uses only physical therapists for its virtual PT offering.

Solutions in this category often offer some connection to in-person care. For example, RecoveryOne refers patients as needed to a preferred network of in-person physical therapists. Both Sword and Hinge have the option to connect with patients' electronic medical records to gather data from in-person encounters, and Hinge offers an in-person house/work call option for patients who prefer live interactions with a licensed provider.

Notably, while Vori offers human-led virtual PT services, its solution is structured differently than others in this category. It offers virtual access to a multidisciplinary care team that pairs physical therapists with physical medicine and rehabilitation doctors (physiatrists) to treat patients with more complex cases and those with chronic pain. In addition to providing virtual PT with real-time tracking by computer vision, Vori providers can prescribe medications and injections, and order medical imaging. Vori primarily contracts through the medical benefit.

All solutions evaluated in the **physical therapist–guided** category have committed to the **American Physical Therapy Association (APTA's)** <u>digital</u> <u>transparency pledge</u>, which commits each organization to labeling PT services according to whether they are performed or directed by licensed physical therapists in accordance with all regulations and APTA's Standards of Practice for Physical Therapy.

**Hinge:** Evidence for Hinge included 12 clinical references, nine of which met inclusion criteria, and also detailed commercial information provided by the company. None of the nine citations compared Hinge data with an in-person PT comparator group. The studies represented a broad set of MSK disorders, including chronic knee, chronic low back, acute MSK pain, and chronic MSK pain.

Two interventional studies compared the Hinge solution with a control group of education and usual care (defined as access to physician visits, pain medications, and imaging). Both citations had durations of 12 weeks and a high risk of bias. In both interventional studies, patients who received the Hinge solution had improvements in pain and function. The pain improvements for the intervention group met MCID in both studies.<sup>109,110</sup>

Four of the seven observational studies of the Hinge solution included comparator groups of nonparticipants. The observational studies primarily reported on pain, function, or both (one citation reported on opioid use). The studies employed a variety of scales and sample sizes and, despite inconsistent reporting of statistical significance, they reported improvement in both pain and function (either from baseline or compared with nonparticipants). Broadly, the direction of evidence for the Hinge solution supports it as superior to no intervention and standard of care, though the evidence is inconclusive relative to in-person PT, as no direct comparison study exists. The solution would benefit from lower risk of bias studies that directly compare the Hinge solution with in-person PT.

Three citations were not included in the primary analysis. Two of these were out of scope, as they focused on postoperative patients<sup>111</sup> and high-frequency impulse

Next Steps

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

therapy.<sup>112</sup> The third citation — a retrospective, longitudinal study with a propensity score-matched comparison group that examined rates of total knee and total hip arthroplasty among patients with osteoarthritis — was not yet available at the time of analysis, but has since been published. It reports statistically significant reductions in rates of total knee and total hip arthroplasty for the digital group compared with a matched control group.<sup>113</sup> This result is consistent with findings from a different Hinge study in which patients with virtual MSK solutions had significantly lower healthcare utilization at one-year follow-up compared with nonparticipant patients in the control group.<sup>114</sup>

Omada: In addition to detailed commercial and company information provided by the company, four citations were considered for Omada, of which two met the inclusion criteria. Both included citations were derived from the same dataset and were observational, longitudinal studies without a comparator group. One citation reported statistically significant improvements in pain and function from baseline.<sup>115</sup> The other citation found that patient engagement positively impacted clinical outcomes, and video visits and provider-patient communication increased platform engagement and patient satisfaction.116

Citations from Omada that did not meet the inclusion criteria included a citation focused on post-operative patients and a microsimulation analysis of the cost savings of virtual PT. The postoperative pain study found that participants aged 60 years or older recorded higher engagement rates and more workouts per week than younger adults.<sup>117</sup> The citation focused on healthcare resources identified the primary drivers of cost savings from virtual PT as early initiation of PT and lower cost of PT.<sup>118</sup> This finding supports the methodological approach and conclusions of the economic analysis of this evaluation.

RecoveryOne: RecoveryOne did not supply company information for this evaluation. Two citations were considered for RecoveryOne, one of which met the inclusion criteria. The included study — a nonrandomized pilot study abstract of 10 participants showed statistically significant changes in pain (VAS) and function (ODI) over four weeks. While the pain outcomes for RecoveryOne appear promising, they are difficult to assess or compare with other companies' results because of the study's short timeframe, small sample size, and the limited information provided by the abstract.<sup>119</sup>

The other RecoveryOne reference focused on postoperative patients, which was out of scope for this assessment. This citation found significantly better return-to-work times for patients who supplemented in-person rehabilitation with online exercise.<sup>120</sup>

**Sword:** Sword provided the largest body of clinical evidence comparing outcomes to in-person PT. Two interventional and 13 observational studies from Sword met the inclusion criteria, in addition to detailed commercial and customer information. The included studies covered acute and chronic low back, shoulder, and hip pain. The two RCTs<sup>121,122</sup> included comparator arms consisting of in-person education, PT, and manual therapy;

one also included cognitive behavioral therapy as appropriate. Both studies were eight weeks in duration and had a medium risk of bias. One study focused on chronic low back pain and found significant improvements in the digital intervention group and the control group for both function (ODI) and pain (NPRS), with both groups, on average, achieving MCID for pain.<sup>123</sup> The other study focused on chronic shoulder pain, and it reported significant improvements and achieved MCID in function (QuickDASH) and pain (three scales) in both arms.<sup>124</sup> Overall, Sword's intervention demonstrated comparable results to in-person PT.

A single prospective database yielded 13 observational studies. One study included a comparator group comprised of a nonparticipant cohort (defined as participants who registered for the program but did not start it). Among the 12 remaining studies, patients who received the intervention showed reductions in NPRS scores, with four studies reporting significant pain improvements from baseline, and five studies reporting that a majority of patients achieved MCID in pain. Five observational studies reported improvement in physical function across multiple scales: four at 12 weeks and another at one year. One comparative observational study found that the digital intervention group achieved greater improvements in pain and function than the nonparticipant comparator group (p-value was not reported).<sup>125</sup> All Sword observational studies (except for Areias, 2022) had a high risk of bias primarily due to group selection bias. The 11 studies were excluded because the study population was outside the scope of this assessment: four studies on

 $\leftarrow$  39  $\rightarrow$ 

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

## **Multidisciplinary Review Teams**

Vori takes a different approach to surgical prevention by providing patients with a multidisciplinary onboarding team that includes physical medicine and rehabilitation physicians, physical therapists, and health coaches/dietitians. This team can prescribe everything from virtual (and in-person) PT to injections, creating multiple pathways to avoid surgery. Results from Vori's study — though limited by sample size and lack of a comparator group — suggest low rates of medication use, imaging, and surgery resulting from the multidisciplinary approach.<sup>133</sup>

patients with primary neurological disorders, four studies on post-surgical patients, and three studies on patients with MSK disorders that were out of scope for the report (elbow, hand/wrist, and ankle).

**Vori:** In addition to companysupplied commercial information, two citations for Vori were considered, one of which met the inclusion criteria. The included citation was a small (n = 36) retrospective observational study examining Vori's virtually delivered interdisciplinary team model. The study, which had a medium risk of bias, found significant pain improvement from baseline (there was no comparator group) and improvements in mental and physical health.<sup>126</sup> Given the limited evidence base for Vori, it is unclear whether further evidence generation will support added benefits for Vori's multidisciplinary approach over time. Notably, Vori has been on the market for a significantly shorter time than other solutions in this category, which may contribute to its smaller evidence base.

The second citation for Vori, a propensity score—matched observational study of chronic back pain, did not meet the inclusion criteria, as there was no digital component of the intervention. The study found that patients evaluated by multidisciplinary teams had significantly shorter time to treatment than those seen by single-discipline teams.<sup>127</sup>

## Summary Findings: Physical Therapist–Guided Solutions

- The literature suggests that the physical therapist-guided solutions deliver clinically meaningful improvements in both pain and function compared with usual care.
- For patients who are receiving in-person PT, these virtual solutions perform comparably across most major indicators, and for some people, they can be reasonably substituted for in-person care.
- Studies by Hinge and Sword compose the bulk of clinical information in the physical-therapist guided solution category, with only Sword providing prospective interventional trials with in-person PT as the control.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

## **RTM-Augmented PT Solutions**

Limber: Unlike the other companies in this report, Limber is designed to augment in-person PT with virtual exercise programs for patients to complete between visits and RTM enablement for providers. Limber is one of the newer companies in the space with the least funding to date. Limber's platform includes automated pathways and technology for patient-facing outcomes collection, home exercise therapy content and programming, and human care managers who support users virtually. While Limber sells primarily to provider groups and health systems (including physical therapists), it also has an offering designed for employers and health plans. Limber has committed to APTA's digital

transparency pledge and has an outcome quality measure specification that is approved for CMS reporting.<sup>128</sup>

The literature review identified one citation for Limber that compared in-person PT supported by their digital solution with in-person care alone.<sup>129</sup> The study reported statistically significant improvements in pain (PROMIS-PI) and function (PROMIS-PF) for the PT plus digital intervention arm compared with the in-person PT control group at an eight-week follow-up. The study had some risk of bias because of deviation from intended intervention and outcomes measurement bias. Limber also supplied commercial and customer information.

## Summary Findings: RTM-Augmented PT Solutions

- While the generalizability of Limber's small study is limited, the evidence suggests that the addition of a digital solution to traditional PT produces superior outcomes for pain and function.
- Further research should focus on understanding the potential patient population that would most benefit from this type of intensive intervention, and the role that the addition of RTM might have on adherence to PT.

## **Preventing Surgery and Other High-Cost Care**

Avoiding unnecessary surgeries and other high-cost interventions is a central goal for patients, employers, and the healthcare system. The Lown Institute has found that back and knee surgeries are among Medicare's most common unnecessary surgeries, including during the COVID-19 pandemic.<sup>130</sup> Data suggest that many surgical interventions result in mixed clinical outcomes for patients and higher healthcare costs for purchasers. The ability to reduce rates of high-cost interventions is a crucial value proposition that virtual MSK solutions present to purchasers. Increasingly, payers, providers, and digital health companies are working to build value-based payment models and risk-bearing contracts for MSK disorders to encourage more upfront PT and low-cost care to avoid surgery and other high-cost interventions.

Most solutions considered in this evaluation state that they aim to reduce high-cost interventions, such as surgeries, and include the associated cost savings in their return on investment (ROI) calculations. For example, Sword submitted multiple case studies and reports suggesting that surgical reduction accounts for 33–60% of their total estimated program savings. Hinge provided a matched cohort analysis suggesting that more than 88% of cost savings were attributable to decreased use of surgery, injections, and emergency room visits.<sup>131</sup> In addition to the cost savings realized from enhanced access to PT and early triage,<sup>132</sup> some solutions employ specialized strategies to reduce surgeries.

**Surgical Intervention Teams.** Some virtual MSK solutions — notably Sword and Hinge — have care teams to counsel patients who are considering care escalation or surgery. Using predictive algorithms and/or claims data, these teams (which often include physicians) attempt to identify patients before they receive a high-cost intervention and provide additional analysis and clinical input to inform patients' decisions.

Unlike the growing body of evidence for the effectiveness of virtual PT, there is little independently verifiable support for the ability or magnitude of virtual MSK solutions to deliver reductions in avoidable surgeries. This does not mean that these savings are not occurring; however, it does mean that our independent analysis of the available evidence does not yet support the conclusion that these interventions are contributing to lower surgical and imaging costs. Practically, such support would require well-designed independent or company-sponsored studies that compare appropriately matched groups that do and do not have access to surgical avoidance programs. Although MSK-related surgeries are relatively low-frequency events compared with other surgeries, they have an outsized impact on potential cost savings.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

#### **Clinical Effectiveness Ratings**

After more than a decade of development, testing, and real-world use, the evidence shows that virtual MSK solutions assessed in this report deliver clinically meaningful improvements in pain and function compared with usual care for people with a range of MSK disorders.

Across the three categories of solutions evaluated, physical therapist-guided solutions can be an effective alternative to in-person PT and have the potential to reduce healthcare spending. The primary health benefits reported in the studies support the use of these virtual solutions as a reasonable substitute for in-person PT to address MSK symptoms of pain and functional limitations for select populations, conditions, and acuity levels, especially when patients cannot (or do not want to) use in-person therapy. The evidence suggests that additional improvements in function and pain may result from pairing in-person and virtual PT (RTM-augmented PT solutions).

Although the findings related to pain and function are largely consistent in this body of evidence, the quality of the studies varied, with a disproportionately high number of observational studies

and a preponderance of studies with medium to high risks of bias. Notably, the prevalence of mixed participant samples — including patients with various MSK disorder types (e.g., low back pain, knee pain) and disparate acuities (e.g., chronic and acute pain) - makes it difficult to isolate the benefits of the digital intervention for individual disorders or patients, in that such benefits may increase or decrease for patients with higher-acuity or complicated MSK pain. Additional well-designed studies with larger sample sizes that focus on specific MSK disorder types and pain acuity would clarify findings about which patient populations are likely to achieve clinically meaningful benefits from virtual MSK care. Given the significant bias in the evidence base, which includes significant selection biases, patient targeting will play a critical role in reproducing benefits.

This assessment uses the ICER Evidence Rating Matrix, which combines evidence certainty and comparative net health benefit to determine the comparative clinical effectiveness of virtual MSK solutions relative to in-person PT. App-based exercise therapy solutions

offer modest evidence that they deliver comparable improvements in pain but no demonstrated improvements in function compared with in-person PT; overall, these solutions are rated as "Comparable or Inferior" to in-person PT.<sup>b</sup> There is a reasonable volume of weak to moderate evidence that physical therapist-guided solutions improve both pain and functional status; overall, these solutions are rated "Comparable or Incremental" compared with in-person PT.<sup>c</sup> There is a very small body of evidence that RTM-augmented PT solutions — when used to augment in-person PT — can produce even better improvements in pain and function than in-person PT, earning these solutions a rating of "Comparable or Better."d

Additional evidence is needed to clarify the limits of virtual versus in-person care in terms of patient complexity and to determine whether there are specific MSK disorders that would particularly benefit from one, the other, or both. Over time, a well-designed randomized trial over a one-year timeframe would help to confirm the clinical efficacy of virtual MSK programs and the patient subgroups that stand to benefit the most from them.

<sup>&</sup>lt;sup>d</sup> This rating corresponds to a C++ in the ICER Evidence Rating Matrix<sup>TM</sup>, meaning there is moderate certainty of a comparable, small, or substantial net health benefit and high certainty of at least a comparable net health benefit.



<sup>&</sup>lt;sup>b</sup> This rating corresponds to a C– the ICER Evidence Rating Matrix<sup>TM</sup>, meaning there is moderate certainty that the net health benefit is either comparable or inferior and high certainty of a comparable net health benefit at best.

<sup>°</sup> This rating corresponds to a C+ in the ICER Evidence Rating Matrix<sup>™</sup>, meaning there is moderate certainty of a comparable or small net health benefit and high certainty of at least a comparable net health benefit.

Economic Impact Summary Ratings

# Economic Impact

MSK conditions lead to increased healthcare spending and challenges completing work and home responsibilities. Back pain — the most common form of MSK pain — affects 39% of all adults in the United States, with disproportionate impacts among older adults (aged 65+), women, and people with low incomes (<100% FPL).<sup>134</sup> Low back pain can lead to additional healthcare utilization, including opioid prescriptions, advanced imaging (e.g., MRI), spinal injections, and back surgery.<sup>135</sup>

Importantly, while the strongest economic evidence focuses on low back pain, the clinical findings above suggest that virtual MSK solutions can be beneficial for a wide range of MSK disorders. This budget model is focused on results for people suffering from low back pain, but the economic impact for other conditions may vary.

As described above, timely access to PT — in-person or virtual — has the potential to not only improve MSK symptoms but also reduce long-term healthcare spending by avoiding unnecessary healthcare utilization. Solutions in this report claim both short- and long-term economic benefits using multiple metrics, including reductions in cost of care and surgical claims, ROI, and per participant savings.

The benefits of PT for both health outcomes and healthcare system spending suggest several opportunities for virtual MSK solutions to produce economic benefits for payers, including:

- 1. Reducing the cost of PT Delivering effective virtual PT services at lower prices and reimbursement rates than in-person PT; and
- 2. Reducing avoidable healthcare spending — Using PT to improve health outcomes and reduce avoidable medical spending for MSK patients on services like surgeries, injections, imaging, and specialist care:
  - a) Improved adherence to PT

**treatment** — Increasing adherence rates among PT patients due to the convenience of care and/or user experience of virtual solutions; and/or

#### b) Better access to PT treatment

— Enabling patients to begin PT sooner after their MSK symptoms begin due to shorter wait times and/or more patient willingness to pursue virtual PT.

The evidence suggests that patients who seek care from a physical therapist before seeing a physician have lower healthcare spending.<sup>136</sup> Understanding how selection issues impact these findings is complex (e.g., people with more serious MSK disorders may be more likely to seek care from a physician than those with less serious disorders). However, it is likely that for some patients, direct access to a physical therapist without needing a referral from a physician may lead to lower overall spending and reduced use of high-intensity medical care.

## Budget Impact Model Methodology

The budget impact model seeks to estimate the expected one- and two-year change in total healthcare spending that results from offering virtual MSK solutions to people suffering from low back pain. The model estimates the number of people who currently use in-person PT for low back pain and could be eligible for virtual MSK solutions. It also estimates the potential savings from substituting in-person care with lower-cost virtual PT for a subset of patients, as well as the reductions in healthcare spending that could be achieved through better adherence and access to virtual PT services. Because the strongest evidence base about PT benefits is related to low back pain, the budget model focuses on this target population.

**Eligible Population:** The population model estimates the number of adults who use PT services to treat low back pain across commercial insurance, Medicare, and Medicaid. This population is the most likely to be able to directly substitute virtual PT for in-person PT. In the United States, an estimated 13% of adults suffer from low back pain annually,

Introduction	Technology Context	Clinical Effectiveness	Economic Impact	Summary Ratings	Next Steps
Exhibit 20					
ESTIMATING	THE ELIGIBLE POPULATION	WITH LOW BACK PAIN F	OR VIRTUAL MSK	SOLUTIONS	
		——— Commercial ——	—— Medicare	——— Medicaid ——	
PERC WHO	ENT OF ENROLLEES ARE ADULTS	78.9%	99.2%	48.7%	
PI	REVALENCE F BACK PAIN	10.4%	24.7%	25.7%	
	PATIENTS WHO USE PT FOR MSK	24.0%	24.0%	24.0%	
	ALL POTENTIAL LOW BACK PAIN VIRTUAL MSK SOLUTION USERS	<b>2.0</b> %	5.9%	3.0%	

including 10% with commercial insurance, 25% of Medicare enrollees, and 26% of adults in the Medicaid population.<sup>137</sup> Among people with low back pain, 24% receive PT services.<sup>138</sup> Therefore, up to 2% of all commercial enrollees, 6% of Medicare beneficiaries, and 3% of Medicaid beneficiaries are receiving PT services for low back pain and could be eligible for virtual PT.<sup>e</sup> While not all patients may be good candidates for virtual PT, these represent estimates of PT users with low back pain who may be eligible for virtual MSK care. When estimating the budget impact of these solutions, we assume a 25% participation rate in virtual MSK solutions among all eligible individuals with low back pain.

Reducing the Cost of PT: Estimated

annual spending for in-person PT among people with MSK conditions is \$1,665 in commercial insurance, \$915 in Medicare, and \$641 in Medicaid. These estimates assume patients receive a PT evaluation and an average of eight visits<sup>139</sup> that are reimbursed at \$101.67<sup>f</sup> per visit in Medicare based on the fee schedule. These rates are adjusted in the model using standard commercial insurance and Medicaid pricing ratios (see methodology in Appendix A). To the extent that virtual PT solutions charge payers less than these prices, they can reduce overall healthcare spending more than the results of this model.

Actual per-person spending for in-person PT varies based on the number of visits and additional services (such as manual manipulation or therapeutic massage) that may be billed by the therapist.

Compared with in-person PT providers, virtual solution providers do not need to pay for building expenses or supplies (e.g., tables, exercise equipment). Further, in-person PT generally requires 1:1 staffing of a physical therapist or PT assistant per patient throughout the session. Because many virtual MSK solutions rely on technology-guided exercise routines and Al-driven patient feedback, they have more efficient labor models and the potential to reduce labor costs. Many virtual solutions use live interactions with physical therapists for intake sessions

<sup>e</sup> Not all Medicaid programs cover RTM.

<sup>1</sup> CPT codes 97161, 97110, 97530, and 97112. PT evaluation (\$101.66); therapeutic exercises to develop strength, endurance, range of motion, and flexibility (\$29.82); therapeutic activities (\$37.62); and neuromuscular re-education (\$34.23). CMS Physician Fee Schedule. Accessed: December 2023.

 $\leftarrow$  44  $\rightarrow$ 

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

and periodic consultations, but most of the exercise sessions are completed asynchronously with data-driven summary reports that allow physical therapists to oversee large numbers of patients at scale. As a result, these solutions can improve labor efficiency, with each licensed physical therapist overseeing larger patient panels than physical therapists who provide in-person care.

#### Pricing Models for Virtual MSK Solutions:

Pricing for virtual MSK solutions varies based on the company, its staffing structure, and its reimbursement model. Some solutions are sold directly to providers who then bill insurance through RTM codes, while many solutions sell directly to employers and health plans on a per-user basis. Solutions sold to employers and health plans may be included in either the medical benefit or the wellness benefit. This section combines published pricing data with proprietary data submitted by the companies for this evaluation. There is limited public pricing information available for the app-based exercise therapy category, and no companies submitted commercial data for these solutions. As of 2023, Kaia for back pain is covered in Germany at a list price of €489.39.<sup>140</sup> U.S.-based pricing is not publicly available for either Kaia or Dario's digital exercise therapy program. Absent sufficient pricing data, this report does not estimate the budget impact of these solutions.

#### The physical therapist-guided solutions

described in this report are sold directly to employers and health plans either through the medical benefit or, more often, the wellness benefit. They generally use a milestone- or tiered-pricing model that includes an initial start-up fee when a user is onboarded into the program plus incremental fees based on the number of sessions completed. Some solutions charge for each session, while others bill after 3–4 sessions and again after 8–9 sessions. Most of these solutions also have a maximum annual charge per user, after which point the user can complete unlimited visits at no additional cost to the purchaser. This pricing model is meant to ensure that charges are tied to utilization and purchasers only pay full price for engaged users who complete multiple sessions.

Within the physical therapist-guided solutions category, list prices for unlimited virtual PT sessions range widely from approximately \$600-\$1,500 per year. Among companies that shared proprietary pricing data, Omada was one of the lower priced solutions Vori was one of the higher priced solutions. Some payers may negotiate discounted rates, and average per-user prices are lower because not all users complete enough sessions to receive the maximum payment. In some cases, these prices include consultations with physicians employed by the virtual solutions (e.g., pain medicine or MSK specialists) in addition to virtual PT visits. While these consultations may help avoid or replace visits with physicians outside of the virtual solutions for some patients, this model does not account for those potential cost savings.

## Medicare RTM Codes and Reimbursement Rates

- 98975 (\$19.97) RTM initial setup and patient education on use of equipment
- 98977 (\$47.27) RTM device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor MSK system; every 30 days
- 98980 (\$50.60) RTM management services, physician/other qualified healthcare professional time requiring at least one interactive communication with the patient/caregiver during the calendar month; first 20 minutes
- 98981 (\$39.95) RTM management services, physician/other qualified healthcare professional time requiring at least one interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

Payments for RTM-augmented PT

**solutions** are structured differently since they are largely sold to in-person providers. These providers purchase access to the technology and bill payers on a fee-for-services basis using RTM codes. The estimated RTM reimbursement for initial set-up and three months of monitoring is \$314–\$433, depending on the amount of time spent.<sup>g</sup>

Some virtual MSK solutions offer outcomes-based contracting models or performance guarantees that tie payments to users' clinical outcomes. The availability, measurement approach, and payment terms of such models vary widely across companies. Performance guarantees are based on member engagement; self-reported user data on satisfaction, pain, function, or surgical intent; or claims-based matched cohort analysis of spending between users and nonusers. While performance guarantees can be complicated to negotiate and adjudicate, they can improve payers' confidence in the economic benefits of virtual MSK solutions and ensure targeted budget savings are achieved.

Reducing Healthcare Spending: As

described above, there is strong evidence that early adoption of PT and improved adherence to PT can result in better clinical outcomes. According to one study, among individuals who had a primary care visit for low back pain and eventually received PT, only one-quarter<sup>141</sup> of patients received early, guidelineadherent care. These patients were much less likely to receive advanced imaging, lumbar spinal injections, surgery, and opioid pain medications than those who received nonadherent or delayed care.

As a result, these patients also had lower healthcare spending related to their low back pain. Compared with patients with delayed, nonadherent care, MSK spending for those with early adherent care was 44% lower, early nonadherent care was 3% lower, and delayed adherent care was 19% lower. This study included 24 months of follow-up and spending reductions associated with early, adherent PT accrued over two years. Virtual MSK solutions have been found to produce similar reductions in spending for people with low back pain due to early versus delayed benefits and improved adherence to PT.142

The budget model includes one year of PT or virtual MSK solutions costs and two years of healthcare related savings. Solutions in the **app-based exercise therapy** and **physical therapist—guided solution categories** — each of which broaden access and convenience for PT — are assumed to improve early initiation of PT by 50% and adherence by 50%. Solutions in the RTM-augmented PT category are assumed to improve adherence by 90% but do not increase early initiation of care.

## **Budget Impact Model Results**

#### App-Based Exercise Therapy

Given the clinical performance of the **app-based exercise therapies** evaluated in this report, there is no current evidence to suggest that these solutions are effective substitutes for people who would otherwise receive in-person PT. However, evidence suggests that exercise-based therapy can improve pain and may reduce downstream healthcare spending associated with physician visits or pain medication and injections. As such, these solutions have the potential to improve health outcomes and decrease spending for people with lower-acuity MSK conditions who might not otherwise pursue PT.

For many health plans and employers, broad distribution of **app-based exercise therapy** solutions across their enrollees may be considered as value-added, albeit cost-additive, similar to discounted gym memberships or other preventive health interventions. At scale, these solutions would need a lower price point to be deployed broadly across the population. Given their relatively low clinical efficacy, they are less likely to reduce utilization of surgeries and other high-cost interventions than other types of solutions.

## Physical Therapist–Guided Solutions

Since pricing across solutions and purchasers varies, the budget model for **physical therapist–guided solutions** includes a low, middle, and high average pricing scenario. For the purpose of the model, the low estimate assumes payers spend \$575 per engaged user. The middle estimate assumes an average annual price of \$995, a 2022 published price for Hinge.<sup>143</sup> To the extent that average per-user pricing for a given payer is lower than this amount, additional savings are possible. Finally, the high estimate assumes average per-user pricing of \$1,144 per year.

Virtual MSK solutions in the physical therapist–guided category have the potential to reduce healthcare spending by lowering the cost of delivering PT.

<sup>a</sup> Assuming three months of management and initial set-up fee in first month (98975); device (98977) and 20 minutes of interactive communication (98980) assumed for low end; and device (98977), 20 minutes of interactive communication (98980), and additional 20 minutes of management (98981) assumed for high end.



Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps
				0	

#### Exhibit 21

## ESTIMATED CHANGE IN ANNUAL HEALTHCARE SPENDING RESULTING FROM ADOPTION OF PHYSICAL THERAPIST-GUIDED SOLUTIONS AT VARIOUS PRICES

		1-YEAR			2-YEAR	
	Commercial	Medicare	Medicaid	Commercial	Medicare	Medicaid
TOTAL PER 1M MEMBERS						
High Solution Price: \$1,144	-\$3.6M	+\$1.6M	+\$3.2M	-\$4.7M	-\$0.1M	+\$2.5M
Middle Solution Price: \$995	-\$4.4M	-\$0.6M	+\$2.0M	-\$5.4M	-\$2.3M	+\$1.4M
Low Solution Price: \$575	-\$6.5M	-\$6.7M	-\$1.1M	-\$7.5M	-\$8.5M	-\$1.7M
PER USER PER YEAR						
High Solution Price: \$1,144	-\$737	+\$111	+\$421	-\$476	-\$4	+\$169
Middle Solution Price: \$995	-\$886	-\$38	+\$272	-\$550	-\$78	+\$94
Low Solution Price: \$575	-\$1,306	-\$458	-\$148	-\$760	-\$288	-\$116
PER MEMBER PER MONTH						
High Solution Price: \$1,144	-\$0.30	+\$0.14	+\$0.26	-\$0.20	\$0	+\$0.11
Middle Solution Price: \$995	-\$0.36	-\$0.05	+\$0.17	-\$0.23	-\$0.10	+\$0.06
Low Solution Price: \$575	-\$0.54	-\$0.56	-\$0.09	-\$0.31	-\$0.35	-\$0.07

Notes. Assumes 25% of in-person PT users shift to virtual MSK platforms, 50% improvement in adherence, and 50% improvement in early initiation of PT. Negative numbers represent healthcare savings (decreased spending).

They can also improve the speed of initiation and adherence to therapy. resulting in lower average healthcare spending across the population of people suffering from low back pain. As Exhibit 21 shows, if one-quarter of eligible users participated in virtual MSK solutions, they could save between \$3.6 million and \$6.5 million per one million commercially insured individuals ---or \$0.30 to \$0.54 per member per month — depending on the solution pricing. Over two years, assuming users continue their health improvements but do not continue to use (and therefore pay for) virtual MSK solutions, the total two-year savings increase from \$4.7 million to \$7.5 million. In the low and middle virtual MSK solution pricing

scenario, these solutions can also save money for the Medicare population, though only the low-price scenario would reduce spending in Medicaid.

These figures represent conservative estimates of potential savings for payers because they are limited to people with low back pain. If virtual MSK solutions can deliver lower-cost PT options and help reduce related healthcare utilization for patients with other MSK challenges, the savings potential would be higher. However, if solutions are broadly deployed and reimbursed for patient populations with lower-acuity that are less likely to experience reductions in healthcare utilization, the overall savings would decrease. Employers who participate in these virtual MSK solutions may also benefit from increased worker productivity and lower absenteeism, factors not captured in this model.

#### RTM-Augmented PT Solutions

Solutions in the **RTM-augmented PT** solutions category are materially different from the other types of solutions because they seek to augment existing in-person PT visits by allowing patients to conduct virtual PT sessions between in-person visits. As a result, there are no possible savings based on reducing the cost of PT for this category, and all savings would result from improved adherence to care.

	YEAR	1 BUDGET IMP	ACT	TWO-YEAR CL	JMULATIVE BUD	OGET IMPACT
	YEAR	1 BUDGET IMP	ACT	TWO-YEAR CU	JMULATIVE BUD	OGET IMPACT
ESTIMATED CHANGE IN ANNUAL HE	YEAR	1 BUDGET IMP		TWO-YEAR CL	JMULATIVE BUE	IONS DGET IMPACT

Note. Assumes 25% of in-person PT users shift to virtual MSK platforms and 90% improvement in adherence. Positive numbers represent increased healthcare spending.

+\$0.31

+\$0.11

+\$0.07

+\$0.19

Evidence suggests that these **RTM**augmented **PT** solutions improve adherence to self-directed exercise at home resulting in improvements in pain and function. As such, the model assumes higher rates of adherence (90%) to PT but no improvement in early initiation of PT since users are enrolled after they begin in-person PT. Assuming the lower end of the RTM billing range, providers could charge an additional \$571 in commercial coverage, \$314 in Medicare, and \$220 in Medicaid (if covered in the state) for RTM in addition to in-person care.

Per Member Per Month

Over two years, these solutions increase spending since they are billed in addition to existing care and the estimated savings from lower healthcare utilization do not offset the increased costs of RTM billing. Assuming 25% adoption of these solutions, in commercial insurance, RTM-augmented PT solutions could increase spending over two years by \$1.7 million per one million members (see Exhibit 22). In Medicare, 25% adoption of RTM-augmented care would increase spending by \$2.8 million per million beneficiaries over two years.

#### Spillover Effects

Another set of potential users for virtual MSK solutions are individuals who would not otherwise have initiated PT at all. This group is the most challenging to model, because some individuals may benefit from improved access to PT and experience lower long-term healthcare spending, whereas others may become active users but would not have needed in-person PT under usual care. Additional research is needed to understand how many users of virtual MSK solutions may be the result of overutilization or unnecessary utilization. While unnecessary utilization of solutions is unlikely to present a safety risk for users, it can increase costs for purchasers if they are paying solution providers on a per-user basis.

+\$0.12

+\$0.04

Further, to achieve cost savings from lower cost virtual PT, solutions must be well-targeted to ensure they are substituting for rather than supplementing in-person care. When virtual MSK solutions are contracted through a wellness benefit, there is potential for payers to be reimbursing both in-person PT providers and virtual solutions for the same patient. In this case, virtual PT costs would be additive and would need to offset their price with improved healthcare benefits resulting from higher patient adherence.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

## Solution-Specific Evidence on Healthcare Savings

Four companies (Hinge, Omada, Sword, Vori) in the **physical therapist–guided solutions category** provided studies estimating the healthcare savings for users of their solutions. Most of these analyses are based on retrospective claims analysis using matched cohort analyses or simulation models. The models each use different methods to estimate the gross MSK-related spending over a 6–24 month period.

Solution-specific estimates vary widely in their methodology (e.g., inclusion criteria, treatment of outliers, and matching approach), which affects reliability of the results. In general, reported savings from these studies should not be compared directly to one another, as differences are likely driven by methodological variance rather than solution-specific performance. Further, these results should always be considered net of the price paid for the solution and may overestimate the actual savings to the purchaser. Contracting with performance guarantees can increase purchaser confidence in the economic benefits of these solutions. Prior to publication, only Sword provided documented evidence of performance guarantees, although other solutions may include performance-based financial components in their contracts.

 Hinge supplied five retrospective economic impact studies using matched cohorts relevant to this analysis. All results are reported net of a \$995 program fee, with estimated savings for Hinge users ranging from \$622 to \$1,682 per year compared to controls. One study conducted by an unnamed actuarial firm included 4,207 members from 136 employers estimated \$1,387 in net annual savings per Hinge enrollee.<sup>144</sup> Another study conducted by Hinge analyzed match cohorts, including 2,925 Hinge users across manufacturing and service sectors, using a large commercial claims dataset. The study estimates net savings for Hinge users of \$992 per year in manufacturing and \$1,682 per year among service sector employees.<sup>145</sup> An analysis of Hinge by the Validation Institute estimated a more modest \$2,224 in gross savings over two years. Assuming the same program fee is only charged once, this would produce \$622 in net annual savings.<sup>146</sup> A small study by Optum examined matched cohort of 87 Medicare fee-for-service beneficiaries using Hinge Health and found that, net of \$995 program costs, the Hinge group spent \$1,660 less than the control group across all conditions.<sup>h,147</sup> A fifth study, a retrospective, longitudinal study focused on total knee arthroplasty and total hip arthroplasty rates, fell outside of the scope of this assessment.

 Omada has a peer reviewed simulation study that estimates
 \$1,116 in gross annual healthcare savings for patients with low back pain and \$1,250 in gross savings across all MSK conditions.<sup>148</sup> The paper cites an example program cost of \$800 including the initial consultation, which would result in net savings of \$316 for low back pain and \$450 across all users. Notably, this study assumed lower rates of surgery across the MSK users, which represents a more conservative and likely realistic savings estimate.

 Sword submitted an economic study performed by Risk Strategies Consulting.<sup>i,149</sup> The study includes data from four clients and uses propensity score matching to compare spending for 2,815 engaged Sword users matched to 5,441 people receiving MSK therapy or PT evaluation. The analysis finds Sword users had \$1,520 in gross annual savings for low back pain, which is roughly \$531 in net savings. Across all MSK conditions, the study estimates \$2,623 in gross MSK savings and \$1,634 net MSK savings per year as a result of higher savings in other MSK types, especially knee, shoulder, and hip. Sword also offers clients a claimsbased performance guarantee.

The Validation Institute analysis of Sword's economic impact compared spending among matched cohorts in the 12 months following their use of the product. The study estimated that Sword users had \$2,472 lower gross spending in the 12 months following the intervention. Net savings would be reduced by the solution price.<sup>150</sup> Sword submitted another five case studies based on results from single employers. These case studies generally reflect Sword net savings estimates comparable to those described above.

<sup>&</sup>lt;sup>h</sup> The study design is limited by the small sample and inclusion of 264 unmatched Hinge Health users in the analysis.
<sup>i</sup> This study was published June 10, 2024 but was submitted to PHTI pre-publication. Figures represent truncated savings excluding MSK spending.

over \$75,000 per year.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

 Vori's conomic analysis, performed by Milliman, estimates \$2,660 in gross savings. The report assumes a \$1,000 example solution price, which would yield \$1,660 in net annual savings.<sup>151</sup>

The significant limitation of these studies is that they cannot account for selection bias within the cohorts on the basis of underlying clinical risk or behavior. Individuals who self-select into a virtual MSK solution may be more engaged in their care, more motivated to pursue conservative care over intensive care, or less clinically complex (making them less likely to require surgery or other high-cost care). As such, these users may be more likely to have lower average MSK spending compared with nonusers, regardless of the digital MSK intervention. Nonetheless, given the widespread evidence about the benefits of early PT and the added efforts that many virtual MSK solutions devote to avoiding surgery and other high-cost care, these solutions are likely to have a positive effect on lowering healthcare spending, even if the savings are less than those described in these company studies.

#### Productivity

This economic analysis does not account for lost work days due to MSK disorders. However, MSK disorders are a common cause of missed work and wages. Effective and convenient MSK care can improve these outcomes. One large study by Omada estimates 7.3 hours of reduced absenteeism for people with low back pain who used a digital MSK solution.<sup>152</sup>

## **Out-of-Pocket Costs**

Patient out-of-pocket costs for accessing virtual MSK solutions vary based on the individuals' insurance and plan design. Generally, most health plans charge cost-sharing for in-person PT sessions and may impose an annual limit on the number of covered therapy visits, regardless of whether they are prescribed by a doctor. In most cases, virtual MSK solutions sold through the wellness benefit are offered free of charge to users. Because these solutions generally provide unlimited access to sessions, they stand to reduce patient out-of-pocket costs and increase the number of covered sessions. Patients who benefit from reduced healthcare utilization and spending may also incur lower out-of-pocket expenses for these avoided medical services. Solutions sold through the medical benefit are likely to be subject to usual cost-sharing, including deductibles and copayments or coinsurance. Patients may also experience savings by eliminating the time and expenses associated with traveling to in-person PT sessions.

## Limitations

This model is constructed using evidence on low back pain and patient populations limited to those suffering from low back pain. Actual MSK disorders are far more prevalent and the actual eligible population for virtual solutions will be much larger. While evidence is limited, there are some studies that find similar potential savings from using digital MSK solutions for neck pain and other joint pain.<sup>153</sup>

Because the healthcare utilization estimates are constructed based on studies of in-person PT adherence, they may under- or over-estimate the savings potential of virtual MSK solutions. Savings estimates produced by the companies in this report generally estimate higher net savings, as described above. Further, these estimates are likely to underestimate the potential savings for low back pain, since the model relies on data from military health system patients who initially sought care from a primary care physician, which is shown to reduce total spending.

This analysis does not take into account long-term (>2 year) health benefits that patients may derive from virtual MSK solutions, including nonfinancial improvements in quality of life and mental well-being. Clinical Effectiveness Economic Impact Summary Ratings

# Summary Ratings

Based on PHTI's review of clinical evidence, the virtual MSK solutions assessed in this report deliver clinically meaningful improvements in pain and function compared with usual care for people with a range of MSK disorders.

Further, across the three categories of solutions evaluated, **physical therapist guided solutions** can be an effective alternative to in-person PT and have the potential to reduce healthcare spending. At the right price, **app-based exercise therapy** may be appropriate for patients with lower-acuity. **RTM-augmented PT** has high clinical efficacy but is likely to increase spending, making it most appropriate for more serious MSK disorders.

App-based exercise therapies can improve pain and function compared with usual care. However, these solutions are unlikely to be effective substitutes for in-person PT, as they have demonstrated improvements only in patients' pain but not function. At an affordable price, these solutions may be effective to provide broad-based virtual care for people with lower-acuity MSK pain, possibly improving patient experience and workplace productivity. Deployed widely across a population, akin to gym membership, they are likely to be cost-additive, given their broad application and limited impact on long-term healthcare spending.

As described in this report, virtual MSK solutions in the physical therapistguided category improve patients' pain and function more than usual care and healing naturally. For patients who are receiving in-person PT, these virtual solutions perform comparably across most major indicators, and for some people, they can be reasonably substituted for in-person care. These solutions also reduce healthcare spending by lowering the cost of PT and improving timely initiation of PT and adherence, which reduces other medical spending. These solutions are likely to improve health equity by delivering PT services to people who may not be able to access in-person therapy.

**RTM-augmented PT solutions,** including Limber and other RTM providers, have limited evidence that shows superior results in pain and functional improvement compared with traditional PT, likely because these solutions encourage more frequent exercise by users. However, because these solutions augment in-person care and are billed in addition to existing treatment, the current evidence suggests they increase healthcare spending. Further evidence regarding the magnitude of potential healthcare savings from these solutions could justify the increased cost, especially if targeted to patients with higher-acuity who are at the greatest risk for complications and treatment escalation.

In terms of health equity and access, virtual MSK solutions have similar rates of week-by-week adherence to in-person PT, however, better engagement as measured by completed sessions per week. Virtual solutions can close access gaps, particularly among older and rural populations or individuals who cannot easily get to in-person PT clinics.

These findings are based on the criteria set forth in the Assessment Framework and the currently available evidence.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

#### Exhibit 23

#### PHTI CATEGORY-LEVEL RATINGS FOR VIRTUAL MSK SOLUTIONS

- Positive 
   Moderate 
   Negative
- Higher Clinical Evidence Certainty
   O Lower Clinical Evidence Certainty

		Clinical Effectiveness	Economic Impact	Summary Rating <sup>b</sup>
<b>App-Based Exercise</b> <b>Therapy</b> <sup>a</sup> Dario, Kaia	0	Results: Improves pain but not function; not substitutable for in-person PTN/AEvidence Certainty: Lower	Pricing data not available	Evidence supports broader adoption depending on price, particularly for patients with lower-acuity MSK conditions
Physical Therapist–Guided Solutions <sup>a</sup> Hinge, Omada, RecoveryOne, Sword, Vori	0	Results: Improves both pain and function; comparable to in-person PT Evidence Certainty: Lower	Decreases net spending relative to in-person PT with savings from avoided care	Evidence supports broader adoption
<b>RTM-Augmented PT</b> <b>Solutions</b> <sup>a</sup> Limber	0	Results: May perform better than in-person PT alone Evidence Certainty: Lower	Increases net spending; savings from avoided care are less than added RTM billing	Ongoing evidence generation needed; may justify broader adoption for patients with higher-acuity MSK conditions

Source: PHTI, Virtual MSK Solutions Assessment, June 2024. See PHTI.org for complete report, methods, and recommendations.

Notes: <sup>a</sup> Not all solutions have clinical data that meet the inclusion standards for this report. Based on the similarity of approaches, it is fair to assume that companies without solution-specific data perform in line with the category. Purchasers and users will have to make their own assumptions about performance. <sup>b</sup> Summary rating reflects the combination of clinical and economic results.

Clinical Effectiveness Economic Impact Summary Ratings Next Steps

# Next Steps

### Realizing Full Potential of Virtual MSK Solutions

Virtual MSK solutions have tremendous potential that has not yet been fully realized. While these solutions market themselves based on improved access, their current business models and user acquisition strategies do not maximize their potential.

Many virtual MSK solutions conduct direct outreach to users through broad marketing efforts, including mass mailings and workplace advertisements. These solutions rarely show up in provider network directories and few physicians refer patients to the programs. Instead, virtual MSK solutions more often conduct targeted marketing based on "claims scrapes" from payers that identify people with MSK-related diagnosis codes, orthopedics visits, or in-person PT visits. Given the delay in claims processing, this targeted outreach can be extremely delayed from the onset of the MSK disorder, thereby reducing the benefits that could be achieved from early PT. Sitting outside of the medical benefit and conducting direct marketing to users does not optimally position these solutions to identify and target the patients who would benefit the most from care.

## Recommendations for Innovators

Integrate into Medical Benefits: Having demonstrated strong clinical benefits for users and the potential to reduce healthcare spending, virtual MSK solutions should increasingly integrate into medical benefits. Such a shift could improve patient identification and increase the portion of people who initiate PT when experiencing MSK-related symptoms by ensuring that virtual solutions are displayed on the health plan or insurance portal website. By unifying virtual MSK and medical claims processing, it also helps avoid duplication of payment between virtual and in-person PT and positions these programs to realize the full potential of their surgical avoidance programs to limit unnecessary utilization.

Coordinating with Providers: Solutions should also work closely with primary care providers and MSK specialists to encourage referrals to PT (virtual or in-person) prior to suggesting other diagnostic or treatment paths. Many people who suffer from MSK disorders begin their journey at a doctor's office, either a primary care provider or an orthopedic specialist. These providers may recommend PT and provide a referral. If providers are more aware of virtual MSK options, they may introduce these options to patients, which could encourage more users to try virtual PT prior to pursuing other treatment.

#### **Tailoring Solutions by Patients' Clinical**

Needs: Some virtual MSK solutions, such as Hinge and Sword, have begun to improve their patient targeting and triage protocols by offering lower priced, lighter touch solutions for people with mild MSK disorders and more comprehensive programs for people with moderate-to-severe needs. Solutions in the app-based exercise therapy category are best suited for individuals with lower acuity, but these solutions may be broadly marketed across the potential patient population. Finally, solutions like Vori and Limber are designing more clinically intensive approaches to manage patients with higher acuity. These solutions may justify higher price points because the potential healthcare savings are higher. Across all scenarios, it is important to calibrate the solution intensity to the patient need to ensure that purchasers are not overpaying for patients with lower acuity and patients with higher acuity are not being undertreated.

Assume Value-Based Risk: While some of the solutions described in this report have begun to offer performance guarantees, the preponderance of payment remains tied to the number of virtual PT sessions a user completes. To demonstrate efficient pricing models, effective patient targeting, and incentives to help users avoid high-cost

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

healthcare utilization, virtual MSK solutions should increasingly embrace value-based payments. Such payments could take the form of claims-based performance guarantees or may involve some solutions accepting full risk for MSK care. Several new companies entering the virtual MSK market are focused on combining in-person and virtual medical care and PT to manage patients' overall spending. Such models are likely to appeal to payers who seek to improve patient outcomes while controlling spending.

Improved Evidence Generation: Despite strong initial indicators that some virtual MSK solutions can perform well relative to in-person PT, the evidence base is limited. Many solutions included in this evaluation did not produce studies with comparator arms (neither in-person PT or no PT). Further, the design of the existing evidence is weak, with no studies having a low risk of bias. While the consistency of findings across the evidence instills confidence that these solutions are clinically effective. the evidence is insufficient to draw conclusions about which subpopulations would benefit most from virtual MSK solutions, how these solutions impact health equity, and what portion of users benefit from lower long-term healthcare spending. Finally, when generating evidence, virtual MSK solutions should prioritize validated measures of primary and secondary health outcomes, rather than measures like surgical intent that are not reliable predictors of future utilization.

## Recommendations for Purchasers

Based on the findings of this evaluation, many virtual MSK solutions offer clinically beneficial alternatives to in-person PT that can improve convenience and access to care for some patients. Many of these solutions — especially those in the physical therapist–guided category — warrant broader adoption and thoughtful contracting to expand their clinical benefits while controlling healthcare spending.

As purchasers consider how to integrate these solutions into their health coverage for plan members or employees, they should ensure solutions are targeted to patients who will benefit most. This requires payment structures that set the right incentives for vendors and coverage models to maximize the clinical benefits of these solutions.

#### **Negotiate for Competitive Prices:**

The virtual MSK solutions assessed in this report vary widely on price, even within the physical therapist-guided category. While the clinical evidence is insufficient to differentiate quality among these solutions, their prices vary widely (nearly twofold). First, purchasers should develop a clear thesis about what problem they want these solutions to address (e.g., patients with higher acuity or lower acuity, broad or focused access, cost reduction or access improvements). Then they should consider product price relative to the target outcomes. For many patients, lower cost solutions may be effective and efficient at meeting their needs.

#### Shift to Value-Based Payments: To

ensure that purchasers derive strong benefits from their MSK investments, they should increasingly contract with performance guarantees or outcomesbased arrangements that tie financial outcomes to clinical performance. The companies providing these solutions are increasingly offering these types of performance guarantees, which should be carefully constructed and adjudicated using claims analysis. Over time, some solutions (including new market entrants) may begin to offer subcapitated arrangements that help ensure the thoughtful integration of virtual and in-person MSK care. Purchasers will need to compare these hybrid solutions with the virtual-first solutions described in this evaluation.

Integration into Medical Benefit: To achieve full clinical benefits from these virtual solutions and avoid doublepaying for PT services, purchasers should begin integrating virtual MSK care into their medical, rather than wellness benefit. Doing so offers several advantages: (1) virtual MSK solutions can be listed in health plan provider networks so people seeking care are directed to their services; and (2) employers and health plans can identify patients who are using in-person PT and may benefit from a virtual option, while also ensuring that they are not doublepaying for services.

Technology Context Clinical Effectiveness Economic Impact Summary Ratings Next Steps

New Marketing Approaches: To

realize the full benefits of virtual MSK solutions, purchasers need to find better approaches to patient identification and outreach to find people who are suffering from MSK disorders before they seek other medical care. Current marketing approaches that rely on claims scrapes or broad marketing across membership are limited in their ability to recruit users. Further, because many patients rely on advice from their doctors, unless virtual MSK solutions are thoughtfully integrated with referring physicians, they will be limited in their ability to redirect care patterns away from highcost interventions or in-person PT. Purchasers should focus on building more effective outreach and patient triage protocols to capture the most benefit from these solutions.

Understand That MSK Solutions That Augment Other Care May Be Cost-Additive: RTM-augmented PT solutions and others that use virtual PT to augment traditional in-person care have strong clinical outcomes but increase overall healthcare spending more than other alternatives. These more intensive and expensive solutions may be beneficial for some patients but should be deployed with caution, as they can increase overall spending. Strong patient targeting - combined with effective financial performance guarantees — could mitigate these risks.

## **Recommendations for Providers**

For some people who suffer from relatively mild or acute MSK disorders, starting treatment with PT before seeing a doctor has positive outcomes. Evidence shows that where a patient initially seeks care can significantly impact their medical journey and cost of care.<sup>154</sup> Providers treating patients with MSK disorders should be aware that early PT may improve pain and function across many MSK conditions, which in turn can reduce unnecessary clinical care, such as advanced imaging, surgery, and steroid injections. Providers should talk with their patients about PT as a treatment option.

For some patients, virtual MSK solutions may be covered by their health plan or employer, offering convenient access to therapy services. Providers should make patients aware of the range of therapy options to identify what works best for them. The best therapy option for each patient will vary based on their health conditions, home and work situation, and personal preferences. Providers should encourage patients to consider a range of therapy options before progressing to additional medical care.

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Economic Impact Summary

Ratings

# List of Appendices

Appendix A Methodology Overview

Appendix B Complete SLR and Company-Submitted Citations

Appendix C Risk of Bias Ratings for SLR Citations

Appendix D Pain Outcomes in SLR

Appendix E Function Outcomes in SLR

Appendix F Key Comparator Studies with Pain Outcomes

Appendix G
Pain Scales: Descriptions and MCID Thresholds

To access all appendices, please visit <u>https://phti.org/</u> <u>assessment/virtual-msk-solutions/#appendices</u>. Appendix H

Key Comparator Studies with Function Outcomes

Appendix I

Function Scales: Descriptions and MCID Thresholds

Appendix J

**Comparator Study Findings by DHT Categories** 

Appendix K Secondary Outcomes

Appendix L User Experience Outcomes in SLR

Appendix M Baseline Patient Characteristics in SLR

Clinical Effectiveness Economic Impact

# References

- <sup>1</sup> Nguyen, Andrew, Izzuddin Aris, Brian Snyder, et al., "Musculoskeletal Health: An Ecological Study Assessing Disease Burden and Research Funding," *The Lancet Regional Health Americas* no. 29 (January 2024): 100661. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10788788/#bib7</u>.
- <sup>2</sup> National Academy of Sciences, "Selected Health Conditions and Likelihood of Improvement with Treatment," *National Academies Press* (April 2020). <u>https://www.ncbi.nlm.nih.gov/books/NBK559512/</u>.
- <sup>3</sup> Atlas, Steven and Richard Deyo, "Evaluating and Managing Acute Low Back Pain in the Primary Care Setting," *Journal of General Internal Medicine* 16, no. 2 (February 2001): 120–131.

https://pubmed.ncbi.nlm.nih.gov/11251764/.

- <sup>4</sup> Hill, Jonathan, David Whitehurst, Martyn Lewis, et al., "Comparison of Stratified Primary Care Management for Low Back Pain with Current Best Practice (STarT Back): A Randomised Controlled Trial," *Lancet* 378, no. 9802 (October 2011): 1560–1571. <u>https://pubmed.ncbi.nlm.nih.gov/21963002/.</u>
- <sup>5</sup> Chou, Roger, Richard Deyo, Janna Friedly, et al., "Nonpharmocologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline," *Annals of Internal Medicine* 166, no. 7 (February 2017): 493–505. <u>https://doi.org/10.7326/M16-2459</u>.
- <sup>6</sup> Kim, Lily, Daniel Vail, and Tej Azad, "Expenditures and Health Care Utilization Among Adults with Newly Diagnosed Low Back and Lower Extremity Pain," *JAMA Network Open 2*, no. 5 (May 2019). <u>https://jamanetwork.com/journals/jamanetworkopen/ fullarticle/2733180</u>.
- <sup>7</sup> Siemieniuk, Reed, Ian Harris, Thomas Agoritsas, et al., "Arthroscopic Surgery for Degenerative Knee Arthritis and Miniscal Tears: A Clinical Practice Guideline" *British Journal* of Sports Medicine 52, no. 5 (March 2018): 313. <u>https://doi.org/10.1136/bjsports-2017-j1982rep</u>.
- <sup>8</sup> Siemieniuk, Reed, Ian Harris, Thomas Agoritsas, et al., "Arthroscopic Surgery for Degenerative Knee Arthritis and Miniscal Tears: A Clinical Practice Guideline," *British Journal* of Sports Medicine 52, no. 5 (March 2018): 313. <u>https://doi.org/10.1136/bjsports-2017-j1982rep</u>.
- <sup>9</sup> Kallmes, David, Bryan Comstock, Patrick Heagerty, et al., "A Randomized Trial of Vertebroplasty for Osteoporotic Spinal Fractures," *The New England Journal of Medicine* 361, no. 6 (August 2009): 569–579. <u>https://doi.org/10.1056/NEJMoa0900563</u>.

- <sup>10</sup> Thorlund, JB, CB Juhl, EM Roos, et al., "Arthroscopic Surgery for Degenerative Knee: Systematic Review and Meta-Analysis of Benefits and Harms," *BMJ* (June 2015): 350. <u>https://doi.org/10.1136/bmj.h2747</u>.
- <sup>11</sup> Goertz, Christine and Steven George, "Insurer Coverage of Nonpharmacological Treatments for Low Back Pain — Time for a Change," *JAMA Network Open* 1, no. 6 (2018): e183037. <u>https://doi.org/10.1001/jamanetworkopen.2018.3037</u>.
- <sup>12</sup> Lin, Ivan, Louise Wiles, Rob Waller, et al., "What Does Best Practice Care for Musculoskeletal Pain Look Like? Eleven Consistent Recommendations from High-Quality Clinical Practice Guidelines: Systematic Review," *British Journal* of Sports Medicine 54 (2020): 79–86. <u>https://doi.org/10.1136/bjsports-2018-099878</u>.
- <sup>13</sup> Zigenfus, Gary, Jiahong Yin, Geneva Giang, et al., "Effectiveness of Early Physical Therapy in the Treatment of Acute Low Back Musculoskeletal Disorders," *Journal of Occupational and Environmental Medicine* 42, no. 1 (January 2000): 35–39.

https://doi.org/10.1097/00043764-200001000-00010.

- <sup>14</sup> Lin, Ivan, Louise Wiles, Rob Waller, et al., "What Does Best Practice Care for Musculoskeletal Pain Look Like? Eleven Consistent Recommendations from High-Quality Clinical Practice Guidelines: Systematic Review," *British Journal of Sports Medicine* 54 (2020): 79–86. https://doi.org/10.1136/bjsports-2018-099878.
- <sup>15</sup> Chou, Roger, Richard Deyo, Janna Friedly, et al., "Nonpharmocologic Therapies for Low Back Pain: A Systematic Review for an American College of Physicians Clinical Practice Guideline," *Annals of Internal Medicine* 166, no. 7 (February 2017): 493–505. <u>https://doi.org/10.7326/M16-2459</u>.
- <sup>16</sup> The Moran Company, "Initial Treatment Intervention and Average Total Medicare A/B Costs for FFS Beneficiaries with an Incident Low Back Pain (Lumbago) Diagnosis in CY 2014" (May 2017).

http://www.aptqi.com/Resources/documents/ APTQI-Complete-Study-Initial-Treatment-Intervention-Lumbago-May-2017.pdf.

<sup>17</sup> Shipton, Edward, "Physical Therapy Approaches in the Treatment of Low Back Pain," *Pain and Therapy* 7, no. 2 (December 2018): 127–137. https://doi.org/10.1007/s40122-018-0105-x.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

<sup>18</sup> ATI Physical Therapy, "42% of Americans Feel Uncomfortable Paying Out-of-Pocket for Chronic Pain Treatment, ATI Physical Therapy National Survey Finds," *Yahoo Finance*, August 4, 2020.

https://finance.yahoo.com/news/42-americans-feel-uncomfortablepaying-165400875.html?guccounter=1&guce\_referrer= aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce\_referrer\_ sig=AQAAAAt-6I9naWec0W7RjOOZd-mX-GvyZEimgWSOFyLsxfmA0z6Xciq7DX46vmSmjHonUwR25NPPPbXQp7MPPng\_Qwa.

<sup>19</sup> American Physical Therapy Association (APTA), "Report Reveals Continued Vacancy Challenges for Outpatient Clinics" (October 2023).

https://www.apta.org/news/2023/10/18/vacancy-report-2023.

<sup>20</sup> Nguyen, Andrew, Izzuddin Aris, Brian Snyder, et al., "Musculoskeletal Health: An Ecological Study Assessing Disease Burden and Research Funding," *Lancet Reg Health Am* 29 (January 2024): 100661. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10788788/.

<sup>21</sup> Peterson-KFF Health System Tracker, "Disease Treatment Costs" (2024).

https://www.healthsystemtracker.org/indicator/spending/ spending-disease-treatment/#Distribution%20of%20total%20 medical%20services%20expenditures%20(US%20\$%20 billions),%20by%20medical%20condition,%202019.

- <sup>22</sup> National Academy of Sciences, "Selected Health Conditions and Likelihood of Improvement with Treatment" (April 2020). <u>https://www.ncbi.nlm.nih.gov/books/NBK559512/</u>.
- <sup>23</sup> Evernorth Research Institute, "Americans in Motion" (2022). <u>https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2022-08/</u> <u>Evernorth%20Americans%20in%20Motion%20Musculoskeletal%20</u> <u>Report\_0.pdf</u>.
- <sup>24</sup> Evernorth, "Americans in Motion." <u>https://d17f9hu9hnb3ar.cloudfront.net/s3fs-public/2022-08/</u> <u>Evernorth%20Americans%20in%20Motion%20Musculoskeletal%20</u> <u>Report\_0.pdf.</u>
- Peterson-KFF Health System Tracker, "Quality of Life" (2024). <u>https://www.healthsystemtracker.org/indicator/health-well-being/</u> <u>years-lived-with-disability/#Age-standardized%20years%20lived%20</u> <u>with%20disability%20(YLD)%20rate%20per%20100,000%20</u> <u>population,%20both%20sexes,%201990-2019</u>.
- <sup>26</sup> National Academy of Sciences, "Selected Health Conditions and Likelihood of Improvement with Treatment" (April 2020). <u>https://www.ncbi.nlm.nih.gov/books/NBK559512/</u>.
- <sup>27</sup> U.S. Bureau of Labor Statistics, "Injuries, Illnesses, and Fatalities" (May 2020). <u>https://www.bls.gov/iif/factsheets/msds.htm</u>.

<sup>28</sup> Garnaes, Kirsti, Siv Mørkved, Torgrim Tønne, et al., "Mental Health Among Patients with Chronic Musculoskeletal Pain and Its Relation to Number of Pain Sites and Pain Intensity, A Cross-Sectional Study Among Primary Health Care Patients," *BMC Musculoskeletal Disorders* 23, no. 1115 (2022).

https://doi.org/10.1186/s12891-022-06051-9.

- <sup>29</sup> Shmagel, Anna, Erin Krebs, Kristine Ensrud, et al., "Illicit substance use in US adults with chronic low back pain," *Spine* 41, no. 17 (September 2016): 1372–1377. <u>https://doi.org/10.1097/BRS.00000000001702</u>.
- <sup>30</sup> Population Reference Bureau (PRB), "Fact Sheet: Aging in the United States" (January 2024).

https://www.prb.org/resources/fact-sheet-aging-in-the-united-states/ #:~:text=The%20number%20of%20Americans%20ages,than%20 it%20has%20ever%20been.

<sup>31</sup> Weinstein, Stuart, Edward Yelin, and Sylvia Watkins-Castillo, "The Burden of Musculoskeletal Diseases in the United States," Fourth Edition, United States Bone and Joint Initiative (2018).

https://www.boneandjointburden.org/fourth-edition/i1/big-picture.

- <sup>32</sup> Girish, Gandikota, Lucas Lobo, Jon Jacobson, et al., "Ultrasound of the Shoulder: Asymptomatic Findings in Men," *American Journal of Roentgenology* 197, no. 4 (October 2011): W713–W719. <u>https://doi.org/10.2214/AJR.11.6971</u>.
- <sup>33</sup> Skou, Søren, Erik Poulsen, Alessio Bricca, et al., "Benefits and Harms of Interventions With Surgery Compared to Interventions Without Surgery for Musculoskeletal Conditions: A Systematic Review with Meta-Analysis" *Journal of Orthopedic and Sports Physical Therapy* 52, no. 6 (June 2022): 312 – 344. <u>https:doi.org/10.2519/jospt.2022.11075</u>.
- <sup>34</sup> Haight, John, Jeanne Sears, Deborah Fulton-Kehoe, et al., "Early High-Risk Opioid Prescribing Practices and Long-Term Disability Among Injured Workers in Washington State, 2002 to 2013," *Journal of Occupational and Environmental Medicine* 62, no. 7 (July 2020): 538–547.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7337121/.

<sup>35</sup> The Moran Company, "Initial Treatment Intervention and Average Total Medicare A/B Costs for FFS Beneficiaries with an Incident Low Back Pain (Lumbago) Diagnosis in CY 2014" (May 2017).

http://www.aptqi.com/Resources/documents/APTQI-Complete-Study-Initial-Treatment-Intervention-Lumbago-May-2017.pdf.

Economic

Impact

Next Steps

- <sup>36</sup> Lin, Ivan, Louise Wiles, Rob Waller, et al., "What Does Best Practice Care for Musculoskeletal Pain Look Like? Eleven Consistent Recommendations from High-Quality Clinical Practice Guidelines: Systematic Review," British Journal of Sports Medicine 54, no. 2 (2020): 79-86. https://bism.bmi.com/content/54/2/79.long.
- 37 Pangarkar, Sanjog, Daniel Kang, Friedhelm Sandbrink, et al., "VA/DoD Clinical Practice Guideline: Diagnosis and Treatment of Low Back Pain," Journal of General Internal Medicine 34 (November 2019): 2620-2629. https://doi.org/10.1007/s11606-019-05086-4.
- 38 American Academy of Family Physicians (AAFP), "Clinical Practice Guideline: Low Back Pain" (April 2017). https://www.aafp.org/family-physician/patient-care/clinicalrecommendations/all-clinical-recommendations/back-pain.html.
- 39 American Academy of Orthopaedic Surgeons (AAOS), "Treatment of Knee Osteoarthritis: A Clinical Practice Guideline from the AAOS," American Family Physician 89, no. 11 (2014): 918-920. https://www.aafp.org/pubs/afp/issues/2014/0601/p918.html.
- 40 American Physical Therapy Association (APTA), "Levels of Patient Access to Physical Therapist Services in the US" (2020).

https://www.apta.org/contentassets/ 4daf765978464a948505c2f115c90f55/direct-access-bystate-map.pdf.

- 41 Gallotti, Marco, Benedetta Campagnola, Antonello Cocchieri, et al., "Effectiveness and Consequences of Direct Access in Physiotherapy: A Systematic Review," Journal of Clinical Medicine 12, no. 18 (September 2023): 5832. https://doi.org/10.3390/jcm12185832.
- <sup>42</sup> U.S. Bureau of Labor Statistics, "Physical Therapists," Occupational Outlook Handbook (2024). https://www.bls.gov/ooh/healthcare/physical-therapists.htm
- <sup>43</sup> LaRosa, John, "U.S. Physical Therapy Clinics Constitute a Growing \$34 Billion Industry," Market Research Blog (July 2019).

https://blog.marketresearch.com/u.s.-physical-therapy-clinicsconstitute-a-growing-34-billion-industry#:~:text=Physical%20 therapy%20salary%20and%20job,growth%20of%2028%25%20 through%202024.

44 APTA, "2022 APTA Benchmark Report: Hiring Challenges in Outpatient Practices" (2022).

https://www.apta.org/apta-and-you/news-publications/reports/2022/ apta-benchmark-report-hiring-challenges.

- <sup>45</sup> U.S. Department of Health and Human Services, Health Resources and Services Administration, National Center for Health Workforce Analysis, "Distribution of U.S. Health Care Providers Residing in Rural and Urban Areas" (2013). https://www.ruralhealthinfo.org/assets/1275-5131/ rural-urban-workforce-distribution-nchwa-2014.pdf.
- <sup>46</sup> Zigenfus, GC, J Yin, GW Giang et al., "Effectiveness of Early Physical Therapy in the Treatment of Acute Low Back Musculoskeletal Disorders," J Occup Environ Med 42, no. 1 (January 2000): 35-39. https://pubmed.ncbi.nlm.nih.gov/10652686/#:~:text=The%20 results%20showed%20that%20patients,work%2C%20and%20 shorter%20case%20duration.
- Bodenheimer, Thomas, Joseph Kucksdorf, Alyssa Torn, et al., "Integrating Physical Therapists Into Primary Care Within a Large Health Care System," Journal of the American Board of Family Medicine, 34, no. 4 (July 2021): 866-870. http://doi.org/10.3122/jabfm.2021.04.200432.
- <sup>48</sup> Szymanek, Eliza, Megan Jones, Casey Shutt-Hoblet, et al., "Implementation of Direct Access Physical Therapy Within the Military Medical System," Military Medicine 187, no. 5-6 (May/June 2022): e649-e654. https://doi.org/10.1093/milmed/usab245.
- <sup>49</sup> Frogner, Bianca, Kenneth Harwood, C. Holly Andrilla, et al., "Physical Therapy as the First Point of Care to Treat Low Back Pain: An Instrumental Variables Approach to Estimate Impact on Opioid Prescription, Health Care Utilization, and Costs," Health Services Research 53, no. 6 (December 2018): 4629-4646.

https://doi.org/10.1111/1475-6773.12984.

- <sup>50</sup> The Alliance for Physical Therapy Quality and Innovation, "Payers: Embrace the Value of Physical Therapy to Reduce Costs," American Journal of Managed Care, (August 2019). https://www.ajmc.com/view/payers-embrace-the-value-of-physicaltherapy-to-reduce-costs.
- <sup>51</sup> Fritz, Julie, Gerard Brennan, and Stephen Hunter, "Physical Therapy or Advanced Imaging as First Management Strategy Following a New Consultation for Low Back Pain in Primary Care: Associations with Future Health Care Utilization and Charges," Health Services Research 50 (March 2015). https://doi.org/10.1111/1475-6773.12301.
- Fritz, Julie, Jaewhan Kim, and Josette Dorius, "Importance of the Type of Provider Seen to Begin Health Care for a New Episode Low Back Pain: Associations with Future Utilization and Costs," Journal of Evaluation in Clinical Practice 22 (September 2015): 247-252. https://doi.org/10.1111/jep.12464.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

<sup>53</sup> Frogner, B.K., Harwood, K., et al., Physical Therapy as the First Point of Care to Treat Low Back Pain: An Instrumental Variables Approach to Estimate Impact on Opioid Prescription, Health Care Utilization, and Costs, 53(6) *Health Serv Res.* 4629-4646 (May 23, 2018). https://doi.org/10.1111/1475-6773.12984.

<sup>54</sup> Childs, John, Julie Fritz, Samuel Wu, et al., "Implications of early and guideline adherent physical therapy for low back pain on utilization and costs," *BMC Health Services Research* 15, no. 150 (April 2015). <u>https://doi.org/10.1186/s12913-015-0830-3</u>.

- <sup>55</sup> Rhon, Daniel and Christopher Tucker, "Nonoperative Care Including Rehabilitation Should Be Considered and Clearly Defined Prior to Elective Orthopaedic Surgery to Maximize Optimal Outcomes," *Arthroscopy, Sports Medicine, and Rehabilitation,* 4, no. 1 (January 2022): e231–e236. <u>https://doi.org/10.1016/j.asmr.2021.09.038</u>.
- <sup>56</sup> APTA, "2022 APTA Benchmark Report: Hiring Challenges in Outpatient Practices" (2022). <u>https://www.apta.org/apta-and-you/news-publications/reports/2022/</u> <u>apta-benchmark-report-hiring-challenges</u>.
- <sup>57</sup> Bove, Allyn, Steven Gough, and Leslie Hausmann, "Providing No-Cost Transport To Patients in an Underserved Area: Impact on Access to Physical Therapy," *Physiotherapy Theory and Practice* 35, no. 7 (March 2018): 645–650. <u>https://doi.org/10.1080/09593985.2018.1457115</u>.
- <sup>58</sup> APTA, "APTA Chapters Fuel State-Level Wins" (2023). <u>https://www.apta.org/article/2023/07/24/state-wins</u>.
- <sup>59</sup> Ashish Vazirani to The Honorable Mike D. Rogers, January 2, 2024, DHA PC PT Report to Congress. <u>https://www.apta.org/siteassets/advocacy/2024/dha\_pc\_pt\_report\_congress\_dec2023.pdf</u>.
- <sup>60</sup> Szymanek, "Implementation of Direct Access Physical Therapy" e649–e654. https://academic.oup.com/milmed/article/187/5-6/e649/6318671.
- <sup>61</sup> Rock Health Digital Venture Funding Database, 2011–2024.
- <sup>62</sup> Pitchbook Data, Inc.
- <sup>63</sup> Page Matthew, Joanne McKenzie, Patrick Bossuyt, et al., "The PRISMA 2020 Statement: An Updated Guideline for Reporting Systematic Reviews," *The BMJ* 372, no. n71 (March 2021). https://doi.org/10.1136/bmj.n71.
- <sup>64</sup> Sterne Jonathan, Jelena Savović, Matthew Page, et al., "RoB 2: A Revised Tool for Assessing Risk of Bias in Randomised Trials," *The BMJ* 366:I4898 (August 2019). <u>https://doi.org/10.1136/bmj.I4898</u>.

<sup>65</sup> Wells, GA, B Shea, D O'Connell, et al., "The Newcastle-Ottawa Scale (NOS) for Assessing the Quality of Nonrandomised Studies in Meta-analyses," The Ottawa Hospital Research Institute.

http://www.ohri.ca/programs/clinical\_epidemiology/oxford.asp.

<sup>66</sup> Werneke Mark, Daniel Deutscher, Deanna Hayes, et al., "Is Telerehabilitation a Viable Option for People with Low Back Pain? Associations Between Telerehabilitation and Outcomes During the COVID-19 Pandemic," *Physical Therapy* 102, no. 5 (February 2022).

https://doi.org/10.1093/ptj/pzac020.

<sup>67</sup> Gruner Marc, Nathan Hogaboom, Ike Hasley, et al., "Prospective, Single-blind, Randomized Controlled Trial to Evaluate the Effectiveness of a Digital Exercise Therapy Application Compared with Conventional Physical Therapy for the Treatment of Nonoperative Knee Conditions," *Archives of Rehabilitation Research and Clinical Translation* 3, no. 4 (August 2021): 100151.

https://doi.org/10.1016/j.arrct.2021.100151.

- <sup>68</sup> Kroenke, Kurt, Jingwei Wu, Matthew Bair, et al., "Reciprocal Relationship Between Pain and Depression: A 12-Month Longitudinal Analysis in Primary Care," *The Journal of Pain* 12, no. 9 (September 2011): 964–973. <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3222454/</u>.
- <sup>69</sup> Kroenke, Kurt, "Improvements in Pain or Physical Function and Changes in Depression and Anxiety Symptoms," JAMA Network Open 6, no. 6 (June 2023): e2320474. <u>https://jamanetwork.com/journals/jamanetworkopen/ fullarticle/2806490</u>.
- <sup>70</sup> Cui, Di, Dora Janela, Fabíola Costa, et al., "Randomized-controlled Trial Assessing a Digital Care Program versus Conventional Physiotherapy for Chronic Low Back Pain," *npj Digital Medicine* 6, no. 121 (July 2023). <u>https://doi.org/10.1038/s41746-023-00870-3</u>.
- <sup>71</sup> Bailey, Jeannie, Vibhu Agarwal, Patricia Zheng, et al., "Digital Care for Chronic Musculoskeletal Pain: 10,000 Participant Longitudinal Cohort Study," *Journal of Medical Internet Research* 22, no. 5 (May 2020): e18250. <u>https://doi.org/10.2196/18250</u>.
- <sup>72</sup> Pak, Sang, Dora Janela, Nina Freitas, et al., "Comparing Digital to Conventional Physical Therapy for Chronic Shoulder Pain: Randomized Controlled Trial," *Journal of Medical Internet Research* 25 (August 2023): e49236. <u>https://doi.org/10.2196/49236</u>.

Introduction	Technology	Clinical	Economic	Summarv	Next
	Context	Effectiveness	Impact	Ratings	Steps
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- <sup>73</sup> Wang, Grace, Manshu Yang, Mindy Hong, et al., "Clinical Outcomes One Year After a Digital Musculoskeletal (MSK) Program: An Observational, Longitudinal Study with Nonparticipant Comparison Group," *BMC Musculoskeletal Disorders* 23, no. 237 (March 2022). https://doi.org/10.1186/s12891-022-05188-x.
- <sup>74</sup> Cui, "Randomized-Controlled Trial Assessing a Digital Care Program."
- <sup>75</sup> Priebe, Janosch, Katharina Haas, Leida Moreno Sanchez, et al., "Digital Treatment of Back Pain versus Standard of Care: The Cluster-Randomized Controlled Trial, Rise-uP," *Journal* of Pain Research 13 (July 2020): 1823–1838. <u>https://doi.org/10.2147/JPR.S260761</u>.
- <sup>76</sup> Pak SS, Janela D, Freitas N, et al. Comparing Digital to Conventional Physical Therapy for Chronic Shoulder Pain: Randomized Controlled Trial. J Med Internet Res. Aug 18 2023;25:e49236.
- <sup>77</sup> Priebe, Janosch, Katharina Haas, Leida Moreno Sanchez, et al., "Digital Treatment of Back Pain versus Standard of Care: The Cluster-Randomized Controlled Trial, Rise-uP," *Journal* of Pain Research 13 (July 2020): 1823–1838. <u>https://doi.org/10.2147/JPR.S260761</u>.
- <sup>78</sup> Priebe, Janosch, Katharina Haas, Leida Moreno Sanchez, et al., "Digital Treatment of Back Pain versus Standard of Care: The Cluster-Randomized Controlled Trial, Rise-uP," *Journal of Pain Research* 13 (July 2020): 1823–1838. https://doi.org/10.2147/JPR.S260761.
- <sup>79</sup> Toelle, Thomas, Daniel Utpadel-Fischler, Katharina-Kristina Haas, et al., "App-based Multidisciplinary Back Pain Treatment versus Combined Physiotherapy Plus Online Education: A Randomized Controlled Trial," *npj Digital Medicine* 2, no. 34 (May 2019). <u>https://doi.org/10.1038/s41746-019-0109-x</u>.
- <sup>80</sup> Shebib, Raad, Jeannie Bailey, Peter Smittenaar, et al., "Randomized Controlled Trial of a 12-week Digital Care Program in Improving Low Back Pain," *npj Digital Medicine* 2, no. 1 (January 2019). https://doi.org/10.1038/s41746-018-0076-7.
- <sup>81</sup> Mecklenburg, Gabriel, Peter Smittenaar, Jennifer Erhart-Hledik, et al., "Effects of a 12-Week Digital Care Program for Chronic Knee Pain on Pain, Mobility, and Surgery Risk: Randomized Controlled Trial," *Journal of Medical Internet Research* 20, no. 4 (April 2018): e156. <u>https://doi.org/10.2196/jmir.9667</u>.
- <sup>82</sup> Cui, "Randomized-Controlled Trial Assessing a Digital Care Program."

- <sup>83</sup> Bates, Nathaniel, Allison Huffman, Evelyn Goodyear, et al., "Physical Clinical Care and Artificial-Intelligence-Guided Core Resistance Training Improve Endurance and Patient-Reported Outcomes in Subjects with Lower Back Pain," *Clinical Biomechanics* 103, no. 105902 (March 2023). <u>https://doi.org/10.1016/j.clinbiomech.2023.105902</u>.
- <sup>84</sup> Zhang, Wei, Som Singh, Amdiel Clement, et al., "Improvements in Physical Function and Pain Interference and Changes in Mental Health Among Patients Seeking Musculoskeletal Care," *JAMA Network Open* 6, no. 6 (June 2023): e2320520. https://doi.org/10.1001/jamanetworkopen.2023.20520.
- <sup>85</sup> Wang G, Yang M, Hong M, Krauss J, Bailey JF. "Clinical Outcomes One Year After a Digital Musculoskeletal (MSK) Program: an observational, longitudinal study with nonparticipant comparison group," *BMC Musculoskelet Disord.*, Mar 11 2022;23(1):237.
- <sup>86</sup> Areias, Anabela, Costa Fabíola, Janela Dora, et al. "Long-Term Clinical Outcomes of a Remote Digital Musculoskeletal Program: An Ad Hoc Analysis from a Longitudinal Study with a Non-Participant Comparison Group," *Healthcare* (*Basel*) 10, no. 12. (November 2022): 10(12) 2349. https://www.mdpi.com/2227-9032/10/12/2349.
- <sup>87</sup> Wang G, Yang M, Hong M, Krauss J, Bailey JF. "Clinical outcomes one year after a digital musculoskeletal (MSK) program: an observational, longitudinal study with nonparticipant comparison group," *BMC Musculoskelet Disord.*, Mar 11 2022;23(1):237.
- <sup>88</sup> Woznica, David, Mark Milligan, Holly Krymis, et al., "Telemedical Interdisciplinary Care Team Evaluation and Treatment of People With Low Back Pain: A Retrospective Observational Study," Archives of Rehabilitation Research and Clinical Translation 5, no. 3 (September 2023): 100269. <u>https://doi.org/10.1016/j.arrct.2023.100269</u>.
- <sup>89</sup> SimpleTherapy, "Debunking the Surgical Intent Metric and Focusing on Real Cost Savings," June 9, 2023. <u>https://web.archive.org/web/20230928221844/https://www. simpletherapy.com/blog/debunking-the-surgical-intent-metric/.</u>
- <sup>90</sup> Wang, Grace, Louie Lu, Laura Gold, et al. "Opioid Initiation Within One Year After Starting a Digital Musculoskeletal (MSK) Program: An Observational, Longitudinal Study with Comparison Group," *Journal of Pain Research* 27, no. 16 (July 2023):2609-2618.

https://doi.org/10.2147/jpr.s412081.

<sup>91</sup> Pak, "Comparing Digital to Conventional Physical Therapy" e49236.

 $\leftarrow$  61  $\rightarrow$ 

6

Economic

Impact

Summary Ratings

- <sup>92</sup> Gruner MP, Hogaboom N, Hasley I, et al. Prospective, Single-blind, Randomized Controlled Trial to Evaluate the Effectiveness of a Digital Exercise Therapy Application Compared With Conventional Physical Therapy for the Treatment of Nonoperative Knee Conditions. *Arch Rehabil Res Clin Transl.* Dec 2021;3(4):100151.
- <sup>93</sup> Toelle TR, Utpadel-Fischler DA, Haas KK, Priebe JA. "App-Based Multidisciplinary Back Pain Treatment Versus combined physiotherapy plus online education: a randomized controlled trial" Article. *npj Digital Medicine*. 2019;2(1).
- <sup>94</sup> Gruner MP, Hogaboom N, Hasley I, et al. Prospective, Single-blind, Randomized Controlled Trial to Evaluate the Effectiveness of a Digital Exercise Therapy Application Compared With Conventional Physical Therapy for the Treatment of Nonoperative Knee Conditions. *Arch Rehabil Res Clin Transl.* Dec 2021;3(4):100151.
- <sup>95</sup> Cui, "Randomized-Controlled Trial Assessing a Digital Care Program." <u>https://doi.org/10.1038/s41746-023-00870-3</u>.
- <sup>96</sup> Pak SS, Janela D, Freitas N, et al. Comparing Digital to Conventional Physical Therapy for Chronic Shoulder Pain: Randomized Controlled Trial. *J Med Internet Res.* 2023;25:e49236. doi:10.2196/49236.
- <sup>97</sup> Areias, Anabela, Dora Janela, Maria Molinos, et al., "Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study," *JMIR Rehabilitation and Assistive Technologies* 10 (August 2023): e49673.

https://doi.org/10.2196/49673.

- <sup>98</sup> Scheer, Justin, Fabíola Costa, Maria Molinos, et al., "Racial and Ethnic Differences in Outcomes of a 12-Week Digital Rehabilitation Program for Musculoskeletal Pain: Prospective Longitudinal Cohort Study," *Journal of Medical Internet Research* 24, no. 10 (October 2022): e41306. <u>https://doi.org/10.2196/41306</u>.
- <sup>99</sup> Scheer, Justin, Anabela Areias, Maria Molinos, et al., "Engagement and Utilization of a Complete Remote Digital Care Program for Musculoskeletal Pain Management in Urban and Rural Areas Across the United States: Longitudinal Cohort Study," JMIR mHealth and uHealth 11 (March 2023): e44316. https://doi.org/10.2196/44316.
- <sup>100</sup> Areias, Anabela, Maria Molinos, Robert Moulder, et al., "The Potential of a Multimodal Digital Care Program in Addressing Healthcare Inequities in Musculoskeletal Pain Management," *npj Digital Medicine* 6, no. 188 (October 2023). <u>https://doi.org/10.1038/s41746-023-00936-2</u>.

- <sup>101</sup> Wang, Grace, Jeannie Bailey, Manshu Yang, et al., "Older Adult Use and Outcomes in a Digital Musculoskeletal (MSK) Program, by Generation, *Frontiers in Digital Health* 3, no. 3 (August 2021): 693170. <u>https://doi.org/10.3389/fdgth.2021.693170</u>.
- <sup>102</sup> Areias AC, Janela D, Molinos M, et al. Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study. *JMIR Rehabil Assist Technol.* 2023;10:e49673. doi:10.2196/49673.
- <sup>103</sup> Areias AC, Janela D, Molinos M, et al, "Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study," *JMIR Rehabil Assist Technol.* 2023;10:e49673. doi:10.2196/49673.
- <sup>104</sup> Mulcahy, Julie, Lauren Beresford, and Anna DeLaRosby, "Defying Stereotypes: Older Adults as Highly Engagers in App-Based Telehealth Physical Therapy," *Topics in Geriatric Rehabilitation* 39, no. 4 (October/December 2023): 307–311. <u>https://journals.lww.com/topicsingeriatricrehabilitation/abstract/ 2023/10000/defying stereotypes older adults as high engagers.10.aspx</u>
- <sup>105</sup> Wang, "Older Adult Use and Outcomes in a Digital Musculoskeletal (MSK) Program, by Generation." <u>https://doi.org/10.3389/fdgth.2021.693170</u>
- <sup>106</sup> Areias AC, Janela D, Molinos M, et al, "Managing Musculoskeletal Pain in Older Adults Through a Digital Care Solution: Secondary Analysis of a Prospective Clinical Study," *JMIR Rehabil Assist Technol.* 2023;10:e49673. doi:10.2196/49673.
- <sup>107</sup> Priebe JA, Haas KK, Moreno Sanchez LF, et al., "Digital Treatment of Back Pain versus Standard of Care: The Cluster-Randomized Controlled Trial, Rise-uP," *J Pain Res.* 2020;13:1823-1838. doi:10.2147/jpr.S260761.
- <sup>108</sup> Toelle, Thomas, Daniel Utpadel-Fischler, Katharina-Kristina Haas, et al., "App-based Multidisciplinary Back Pain Treatment versus Combined Physiotherapy Plus Online Education: A Randomized Controlled Trial," *npj Digital Medicine* 2, no. 34 (May 2019). https://doi.org/10.1038/s41746-019-0109-x.
- <sup>109</sup> Mecklenburg G, Smittenaar P, Erhart-Hledik JC, Perez DA, Hunter S. Effects of a 12-Week Digital Care Program for Chronic Knee Pain on Pain, Mobility, and Surgery Risk: Randomized Controlled Trial. *J Med Internet Res.* 2018;20(4):e156. doi:10.2196/jmir.9667.
- <sup>110</sup> Shebib R, Bailey JF, Smittenaar P, et al., "Randomized Controlled Trial of a 12-Week Digital Care Program," *npj Digit Med.* 2019;2:1.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

- <sup>111</sup> Hong, Mindy, Joey Loeb, Manshu Yang, et al., "Postoperative Outcomes of a Digital Rehabilitation Program After Total Knee Arthroplasty: Retrospective, Observational Feasibility Study," *JMIR Formative Research* 6, no. 9 (September 2022): e40703. https://doi.org/10.2196/40703.
- <sup>112</sup> Amirdelfan, Kasra, Mindy Hong, Bobby Tay, et al., "High-Frequency Impulse Therapy for Treatment of Chronic Back Pain: A Multicenter Randomized Controlled Pilot Study," *Journal of Pain Research* 14 (September 2021): 2991–2999. <u>https://doi.org/10.2147/JPR.S325230</u>.
- <sup>113</sup> Lu, Louie, Laura Gold, Karl Koenig, et al., "Digital Musculoskeletal Program Is Associated With Decreased Joint Replacement Rates," *American Journal of Managed Care* 30, no. 4 (October 2023): e103–e108. <u>https://doi.org/10.37765/ajmc.2024.89463</u>.
- <sup>114</sup> Wang, "Clinical Outcomes One Year After a Digital Musculoskeletal (MSK) Program" 237. <u>https://doi:10.1186/s12891-022-05188-x</u>.
- <sup>115</sup> Beresford, Lauren and Todd Norwood, "Can Physical Therapy Deliver Clinically Meaningful Improvements in Pain and Function Through a Mobile App? An Observational Retrospective Study," Archives of Rehabilitation Research and Clinical Translation 4, no. 2 (June 2022): 100186. <u>https://doi.org/10.1016/j.arrct.2022.100186</u>.
- <sup>116</sup> Beresford, Lauren and Todd Norwood, "The Effect of Mobile Care Delivery on Clinically Meaningful Outcomes, Satisfaction, and Engagement Among Physical Therapy Patients: Observational Retrospective Study," *JMIR Rehabilitation and Assistive Technologies* 9, no. 1 (January–March 2022): e31349. <u>https://doi.org/10.2196/31349</u>.
- <sup>117</sup> Mulcahy J, Delarosby A, Beresford L. "Defying Stereotypes: Older Adults as Highly Engagers in App-Based Telehealth Physical Therapy. Topics in Geriatric Rehabilitation" (2023).
- <sup>118</sup> Chen, Fang, Cynthia Veronica Siego, Carolyn Jasik, et al., "The Value of Virtual Physical Therapy for Musculoskeletal Care," *American Journal of Managed Care* 29, no. 6 (June 2023): e169–e175.

https://doi.org/10.37765/ajmc.2023.89375.

<sup>119</sup> Bray, Jonathan, "Impact of Using an Online Interactive Rehabilitation Program for Low Back Pain Compared with Traditional Physical Therapy: A Pilot Study," *Archives* of *Physical Medicine and Rehabilitation* 102, no. 4 (April 2021): e13.

https://doi.org/10.1016/j.apmr.2021.01.040.

- <sup>120</sup> Anderson, Lesley, Sean Kinsman, and Michael Oberlander, "Postoperative Compliance and Return to Work After Rotator Cuff Repair: Value of an Interactive Online Rehabilitation Program Among Patients Treated Under Workers' Compensation," *Orthopedics* 44, no. 2 (March– April 2021): e197–e202. https://doi.org/10.3928/01477447-20201119-07.
- <sup>121</sup> Cui, "Randomized-Controlled Trial Assessing a Digital Care Program."
- <sup>122</sup> Pak, "Comparing Digital to Conventional Physical Therapy" e49236.
- <sup>123</sup> Cui, "Randomized-Controlled Trial Assessing a Digital Care Program."
- <sup>124</sup> Pak, "Comparing Digital to Conventional Physical Therapy" e49236.
- <sup>125</sup> Areias AC, Costa F, Janela D, et al. Long-Term Clinical Outcomes of a Remote Digital Musculoskeletal Program: An Ad Hoc Analysis from a Longitudinal Study with a Non-Participant Comparison Group. *Healthcare (Basel)*. Nov 23 2022;10(12).
- <sup>126</sup> Woznica, "Telemedical Interdisciplinary Care Team Evaluation" 100269.
- <sup>127</sup> Naidu, Ishan, Jessica Ryvlin, Devin Videlefsky, et al., "The Effect of a Multidisciplinary Spine Clinic on Time to Care in Patients with Chronic Back and/or Leg Pain: A Propensity Score-Matched Analysis," *Journal of Clinical Medicine* 11, no. 9 (May 2022): 2583.

https://www.mdpi.com/2077-0383/11/9/2583.

- <sup>128</sup> Limber Health, "For Providers" *Accessed* May 2024. <u>https://www.limberhealth.com/for-providers/qcdr</u>.
- <sup>129</sup> Gruner, "Prospective, Single-Blind, Randomized Controlled Trial" 100151.
- <sup>130</sup> Lown Institute Hospitals Index, "Hospital Overuse During COVID" (May 2022). <u>https://lownhospitalsindex.org/2022-winning-hospitalsvoiding-overuse/.</u>
- <sup>131</sup> Hinge Health, "Validation Institute Independently Validates Hinge Health Outcomes" (June 2021). <u>https://www.hingehealth.com/resources/press-releases/validation-institute-proven-to-reduce-medical-claims/</u>.
- <sup>132</sup> Childs, John, Julie Fritz, Samuel Wu, et al., "Implications of early and guideline adherent physical therapy for low back pain on utilization and costs," *BMC Health Services Research* 15, no. 150 (April 2015).

https://doi.org/10.1186/s12913-015-0830-3.

Introduction	Technology	Clinical	Economic	Summary	Next
	Context	Effectiveness	Impact	Ratings	Steps

- <sup>133</sup> Woznica DN, Milligan M, Krymis H, Peters KC, O'Connor MI, Grant RA. "Telemedical Interdisciplinary Care Team Evaluation and Treatment of People With Low Back Pain: A Retrospective Observational Study," *Arch Rehabil Res Clin Transl.* 2023;5(3):100269. doi:10.1016/j.arrct.2023.100269.
- <sup>134</sup> Lucas, Jacqueline, Eric Connor, and Jonaki Bose, "Back, Lower Limb, and Upper Limb Pain Among U.S. Adults, 2019," Centers for Disease Control and Prevention, National Center for Health Statistics (NCHS) Data Brief no. 415 (July 2021). https://www.cdc.gov/nchs/products/databriefs/db415.htm.
- <sup>135</sup> Traeger, Adrian, Rachelle Buchbinder, Adam Elshaug, et al., "Care for Low Back Pain: Can Health Systems Deliver?" *Bull World Health Organ* 97, no. 6 (June 2019): 423–433. <u>https://doi.org/10.2471/BLT.18.226050</u>.
- <sup>136</sup> The Moran Company, "Initial Treatment Intervention and Average Total Medicare A/B Costs for FFS Beneficiaries with an Incident Low Back Pain (Lumbago) Diagnosis in CY 2014" (May 2017).

http://www.aptqi.com/Resources/documents/APTQI-Complete-Study-Initial-Treatment-Intervention-Lumbago-May-2017.pdf.

- <sup>137</sup> Calculated from Shmagel, Anna, Robert Foley, and Hassan Ibrahim, "Epidemiology of Chronic Low Back Pain in US Adults: Data from the 2009–2010 National Health and Nutrition Examination Survey," *Arthritis Care and Research* 68, no. 11 (November 2016): 1688–1694. <u>https://doi.org/10.1002/acr.22890</u>.
- <sup>138</sup> Sharpe, Jason, Brook Martin, Julie Fritz, et al., "Identifying Patients Who Access Musculoskeletal Physical Therapy: A Retrospective Cohort Analysis," *Family Practice* 38, no. 3 (June 2021): 203–209. https://doi.org/10.1093/fampra/cmaa104.
- <sup>139</sup> Chen, Fang, Cynthia Veronica Siego, Carolyn Jasik, et al., "The Value of Virtual Physical Therapy for Musculoskeletal Care," American Journal of Managed Care 29, no. 6 (June 2023): e169–e175. <u>https://doi.org/10.37765/ajmc.2023.89375</u>.

<sup>140</sup> Groene, Nicole and Luca Schneck, "Covering Digital Health Applications in the Public Insurance System: How to Foster Innovation in Patient Care While Mitigating Financial Risks— Evidence from Germany," *Frontiers in Digital Health* 5 (October 2023): 1217479. <u>https://doi.org/10.3389/fdgth.2023.1217479</u>.

<sup>141</sup> Childs JD, Fritz JM, Wu SS, Flynn TW, Wainner RS, Robertson EK, Kim FS, George SZ. Implications of early and guideline adherent physical therapy for low back pain on utilization and costs. *BMC Health Serv Res.* 2015 Apr 9;15:150. <sup>142</sup> Chen, Fang, Cynthia Veronica Siego, Carolyn Jasik, et al., "The Value of Virtual Physical Therapy for Musculoskeletal Care," *American Journal of Managed Care* 29, no. 6 (June 2023): e169–e175.

https://doi.org/10.37765/ajmc.2023.89375.

- <sup>143</sup> Curran, Patrick and Heidi Laughlin, "Hinge Health Medicare Cost and Utilization Study," *Optum* (April 2022). <u>https://assets.ctfassets.net/cad7d5zna5rn/6BN7T0unYTlqPc EFDmNw54/8a16f0f497294d25f9838871b7b053c2/ Hinge Health Medicare Cost and Utilization Study.pdf.</u>
- <sup>144</sup> Hinge Health, "Digital Musculoskeletal Impact on Medical Claims: 136 Employer Study," (2022). <u>https://go.hingehealth.com/136-employer-study#:~:text=The%20</u> <u>largest%2Dever%20medical%20claims,delivering%20a%20</u> <u>2.4x%20ROI</u>.
- <sup>145</sup> Hinge Health, "Manufacturing and Services Industries Medical Claims ROI Study," (2023). <u>https://go.hingehealth.com/l/730343/2023-03-28/8tsjnc/730343/</u> <u>1680035576fiT2VNBW/MedicalClaimsROI\_2023.pdf</u>.
- <sup>146</sup> Hinge Health, "Validation Institute Independently Validates Hinge Health Outcomes," (June 2021). <u>https://www.hingehealth.com/resources/press-releases/validation-institute-proven-to-reduce-medical-claims/.</u>
- <sup>147</sup> Curran, "Hinge Health Medicare Cost and Utilization Study." <u>https://assets.ctfassets.net/cad7d5zna5rn/6BN7T0unYTlqPc</u> <u>EFDmNw54/8a16f0f497294d25f9838871b7b053c2/</u> <u>Hinge Health Medicare Cost and Utilization Study.pdf.</u>
- <sup>148</sup> Chen, Fang, Cynthia Veronica Siego, Carolyn Jasik, et al., "The Value of Virtual Physical Therapy for Musculoskeletal Care," *American Journal of Managed Care* 29, no. 6 (June 2023): e169–e175. https://doi.org/10.37765/ajmc.2023.89375.
- <sup>149</sup> Risk Strategies Consulting, "Assessment of Medical Cost Savings from Sword's MSK Interventions," (June 2024). <u>https://go.swordhealth.com/rs/675-GJP-011/images/Sword%20</u> <u>Health%20Medical%20Cost%20Savings%20Study%20June%20</u> <u>2024?version=0</u>.
- <sup>150</sup> Validation Institute, "Review for: SWORD Health Validation Achieved: Savings Through: July 2023," (2022). <u>https://validationinstitute.com/wp-content/uploads/2021/02/</u> <u>Sword-Health-final.pdf</u>.
- <sup>151</sup> Barrington, Austin, Deana Bell, and Austin Levenson, "Independent review of methodology for quantifying financial impact of the Vori Health musculoskeletal care pathways program," *Milliman* (January 2023).

https://www.milliman.com/en/insight/review-of-methodologyfor-financial-impact-of-vori-health-musculoskeletal.

Economic Impact Summary Ratings Next Steps

- <sup>152</sup> Chen F, Siego CV, Jasik CB, et al. The Value of Virtual Physical Therapy for Musculoskeletal Care. Am J Manag Care. 29, no. 6 (2023): e169-e175.
- <sup>153</sup> Chen F, Siego CV, Jasik CB, et al. The Value of Virtual Physical Therapy for Musculoskeletal Care. Am J Manag Care. 29, no. 6 (2023): e169-e175.
- <sup>154</sup> Harwood, Kenneth J, Jesse Pines, J.M. Andrilla, C. Holly Andrilla, et al., "Where to start? A two stage residual inclusion approach to estimating influence of the initial provider on health care utilization and costs for low back pain in the US," *BMC Health Services Research* 22, no. 694 (2022).

https://bmchealthservres.biomedcentral.com/ articles/10.1186/s12913-022-08092-1.

