mymobility®

Care Management Platform in Joint Arthroplasty

US Payer Dossier

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List of Abbreviations

Abbreviation	Definition
AAOS	American Academy of Orthopaedic Surgeons
ACL	Anterior cruciate ligament
AHRQ	Agency for Healthcare Research and Quality
AJRR	American Joint Replacement Registry
ASES	American Shoulder and Elbow Score

Abbreviation	Definition
BCBS	Blue Cross Blue Shield
BMI	Body mass index
BMUS	Burden of Musculoskeletal Diseases in the US
CCI	Charlson Comorbidity Index
CFR	Code of Federal Regulations
CHIRP	Canary Health Implanted Reporting Processor
CI	Confidence interval
CJR	Comprehensive Joint Replacement
CMS	Centers for Medicare & Medicaid Services
COPD	Chronic obstructive pulmonary disease
CPT	Current Procedural Technology
CRQ	Chronic Respiratory Questionnaire
CTE	Canturio™ Tibial Extension
DASH	Disabilities of the Arm, Shoulder, and Hand
DMPAG	Digital Medicine Payment Advisory Group
DVT	Deep vein thrombosis
EHR	Electronic Health Record
E/M	Evaluation and management
EQ-5D	EuroQol–5 Dimensions
EQ-5D-5L	EuroQol–5 Dimensions–5 Levels
ER	Emergency room
FDA	Food and Drug Administration
FFS	Fee-for-service
GBD	Global Burden of Disease
GPS	Global positioning system
HCRU	Healthcare resource use
HCUP	Healthcare Cost and Utilization Project
HIPAA	Health Insurance Portability and Accountability Act
HOOS JR	Hip Disability and Osteoarthritis Outcome Score – Joint Replacement
HSS	Hospital for Special Surgery
IKDC	International Knee Documentation Committee
IM	Intramedullary
KFF	Kaiser Family Foundation
K-L	Kellgren-Lawrence
KOOS JR	Knee Injury and Osteoarthritis Outcome Score – Joint Replacement
LCD	Local coverage determinations
LEAS	Lower Extremity Activity Scale
LEFS	Lower Extremity Functional Scale
LOS	Length of stay

Abbreviation	Definition
MCID	Minimal clinically important difference
MCO	Managed care organization
MCS	Mental Component Summary
MRI	Magnetic resonance imaging
MUA	Manipulation under anesthesia
NA	Not applicable
NCD	National coverage determination
NHANES	National Health and Nutrition Examination Survey
NHDS	National Hospital Discharge Survey
NIS	National Inpatient Sample
NPWT	Negative pressure wound treatment
NR	Not reported
NRS	Numeric rating scale
NSAID	Non-steroidal anti-inflammatory drugs
NSQIP	National Surgical Quality Improvement Program
NTAP	New technology add-on payment
OA	Osteoarthritis
ORIF	Open reduction and internal fixation
PCS	Physical Component Summary
PEP	Patient Engagement Platforms
PKA	Partial knee arthroplasty
PROM	Patient-reported outcome measure
PROMIS-10	Patient-Reported Outcomes Measurement Information System–10
PT	Physiotherapy
PTSD	Post-traumatic stress disorder
QoL	Quality of life
RCT	Randomized controlled trial
ROM	Range of motion
RPM	Remote patient monitoring
RTM	Remote therapeutic monitoring
SABA	Short-acting beta agonist
SANE	Single assessment numeric evaluation
SD	Standard deviation
SF-12	Short Form 12
SLS	Single Leg Stance
SoC	Standard of care
SST	Simple Shoulder Test
THA	Total hip arthroplasty
TKA	Total knee arthroplasty

Abbreviation	Definition
TUG	Timed Up and Go test
UK	United Kingdom
US	United States
VAS	Visual analog scale
VERITAS	Virtual Exercise Rehabilitation In-home Therapy
VO_2	Maximal oxygen consumption
VR-12	Veterans RAND 12 Item Health Survey
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
WOSI	Western Ontario Shoulder Instability Index

Executive Summary

Burden of Illness: Osteoarthritis (OA) is a degenerative and debilitating disease,[1,2] affecting approximately 51.9 million people in the US, more half of whom are working-age adults (18 to 64 years).[3] The most common joints affected by OA are the knee, hip, hands, lower back, and neck.[1,2]

Joint replacement surgery, which can improve pain and restore mobility to the affected joint, is the standard of care (SoC) treatment for patients who no longer respond to more conservative therapies.[2,4-6]

- Total knee arthroplasty (TKA): the gold standard treatment for patients with severe knee OA
- Partial knee arthroplasty (PKA): may be used to treat OA affecting a single compartment of the knee
- Total hip arthroplasty (THA): the gold standard treatment for severe end-stage OA of the hip

Joint arthroplasty is among the most common elective procedures in the US;[7] per the 2022 AAOS (American Academy of Orthopaedic Surgeons)/AJRR (American Joint Replacement Registry) report, which includes data from over 1,400 surgical sites, over 2.5 million primary and revision hip and knee procedures were reported between 2012 and 2021.[8]

Per National Inpatient Sample (NIS) data, 5.9 million TKA procedures and 2.8 million THA procedures were performed between 2006 and 2015.[9,10] The utilization of hip and knee arthroplasty has increased at a rapid pace in recent years and is projected to continue growing annually, [7,10-14] with adults <65 years of age representing the fastest growing demographic.[15,16] As utilization of primary joint arthroplasty has increased, particularly at younger ages, utilization of revision surgeries (which currently account for 9% of TKA procedures and 11% THA procedures, per AJRR data) is also expected to increase.[8,10,17,18]

The clinical burden of joint arthroplasty includes both unresolved OA symptoms and potential surgical complications, some of which require readmission and/or revision surgery. Post-TKA complications include, but are not limited to persistent pain, stiffness, instability, and swelling, to surgical site infection, blood loss, and thromboembolism;[19-21] in two retrospective studies, post-operative complications were reported in 47% to 54% of TKA recipients.[20,21] Post-TKA stiffness, often linked to suboptimal rehabilitation, has required manipulation under anesthesia (MUA) in approximately 4% of patients.[22-24] Complications also impact a sizeable subset of hip arthroplasty patients, with nearly 8% of THA recipients requiring readmission within 90 days post-procedure in a Medicare claims analysis.[25]

In addition to its clinical burden, OA is also a costly disease: per the Burden of Musculoskeletal Diseases in the US (BMUS), the total incremental cost associated with OA between 2008 and 2014 was $136.8 billion per year, with the largest percentage of OA-related direct medical costs attributable to joint arthroplasty.[26] Published calculations using Agency for Healthcare Research and Quality (AHRQ) data estimated that TKA and THA were associated with $28.5 billion and $13.7 billion in hospital expenditures, respectively, in 2009.[27] The economic burden of joint arthroplasty is driven by both hospitalization and post-acute care costs, which have accounted for nearly half of total episode-of-care costs and contribute substantially to variations in payer reimbursement.[28-31] In the year following joint arthroplasty, both payers and patients have continued to incur considerable costs, with the majority attributed to outpatient physiotherapy (>70% of total outpatient costs in one randomized clinical trial).[32] Revision surgeries contribute disproportionately to the cost burden of joint arthroplasty, with higher hospital costs and healthcare resource use (HCRU),[33,34] and TKA recipients who undergo MUA require additional HCRU and have a particularly high risk of revision surgery.[22-24]

Unmet Need: Alleviating the patient burden and resource use of traditional physiotherapy remains a key unmet need in patients recovering from joint arthroplasty. The burden of in-person physiotherapy impacts both patients and caregivers, as traditional outpatient rehabilitation includes 6 weeks of clinic-based appointments, during which patients are typically not permitted to drive.[29] Furthermore, delayed or inadequate post-surgical rehabilitation may further increase HCRU and costs; a 2016 systematic literature review and meta-analysis of knee and hip arthroplasty noted longer length of stay (LOS) with standard rehabilitation (commencing on either post-operative day one or post-operative day two) compared to early initiation of rehabilitation (commencing on the day of surgery or post-operative day one).[35]

The need for more integrated and effective post-surgical follow-up is highlighted by the trend towards reduced LOS following joint arthroplasty (to a mean 1.3 days for TKA, 0.6 days for PKA, and 1.4 days for THA),[29,36] with more procedures performed in the outpatient setting and higher rates of home discharge, leaving a gap in post-surgical follow-up and support.[34,36-38] Recent surveys have also shown that patients increasingly prefer and expect digital engagement in the healthcare setting, particularly with outpatient surgeries, but availability of these services has lagged demand.[39-42]

Most critically, improvement in patient outcomes and mitigation of risks remains a key unmet need in joint arthroplasty.

- Physicians have been shown to overestimate improvements in pain and function relative to patients, underscoring the importance of patient-reported outcome measures (PROMs) to inform decision-making.[43]
- Patients have reported high rates of dissatisfaction with joint arthroplasty (1 in 5 post TKA, and 1 in 4 younger patients), driven primarily by insufficient functional improvement, inadequate pain relief, and unmet expectations;[44-46] notably, patients who were less active post-TKA were more likely to be dissatisfied.[44]
- Given that 90% of post-operative recovery takes place outside the purview of healthcare providers, and verification of patient compliance is particularly challenging with traditional care models, connected digital pathways are critical to continuity of care.[29,47]

- Digital patient engagement following joint arthroplasty has demonstrated significant reductions in both costs and complications*;[48,49] however, these technologies have yet to be widely implemented in clinical practice.

Product Information: mymobility® is a care management platform that connects patients receiving surgical procedures with their care team via smartphone and optional Apple Watch® wearable wrist band, guiding and engaging patients throughout the episode of care and providing clinicians with continuous data and patient-reported feedback (Section 2.2).[50-52]

- Pre-procedure, mymobility offers patient education, individualized exercises, and direct communication with the care team, to optimize patient engagement and help patients prepare for surgery.[50,51]
- Post-procedure, mymobility tracks both patient-reported outcomes and passively collected objective metrics, allowing clinicians to continuously monitor patient recovery (and set automatic exceptions for patients who fall below set threshold for gait quality and pain management), and provide self-directed in-app exercises to replace or supplement in-person physical therapy.[50,51,53]

The mymobility software platform is registered and defined as a medical device by the Food and Drug Administration (FDA) and fits the requirements of a remote therapeutic monitoring (RTM) device.[54-57] Physicians and other qualified healthcare personnel may bill for mymobility using the current procedural codes (CPT) codes for RTM services to monitor the musculoskeletal system (subject to coding requirements).[57] mymobility also integrates seamlessly into ZBEdge™ Dynamic Intelligence™, a connected suite of digital and robotic technologies (WalkAI™ Artificial Intelligence†, OrthoIntel Orthopedic Intelligence Platform, ROSA® Robotics System, and Persona IQ® The Smart Knee®) that unlocks the full potential of Zimmer Biomet's cutting edge digital technologies, robotics and implant solutions, further augmenting the value provided by the mymobility platform.[58-61]

Clinical Value: Data supporting the clinical value of mymobility in joint arthroplasty is available from a prospective, multicenter randomized controlled trial (RCT; N=817), designed to evaluate whether mymobility-guided education and exercise, paired with remotely captured activity data, offers a clinically effective alternative to the current SoC while reducing overall HCRU.[62,63] Follow-up is also ongoing from a larger correlative cohort (N=6,601), as mymobility facilitates tracking of patient recovery parameters for up to 1 year post-procedure; the goal of these secondary analyses is to develop correlative measures that will aid surgeons in better understanding and managing risk in their patient populations.[64]

In the RCT cohort of the clinical trial, mymobility demonstrated clinical, functional, and quality of life (QoL) outcomes comparable to traditional care models in both knee and hip arthroplasty:[62,65,66]

- In TKA/PKA recipients, mymobility was associated with comparable functional outcomes vs SoC follow-up, with no significant difference in KOOS JR (Knee Injury and Osteoarthritis Outcome Score – Joint Replacement) scores through 1 year post-surgery, and no significant difference in single leg

*Note that mymobility has not been clinically evaluated to reduce complications.

†WalkAI is available for patients undergoing a hip or knee replacement using the mymobility app on an iPhone 8 or higher supported by the current or previous version of iOS.

stance (SLS) times, Timed Up and Go test scores, and mean passive flexion through 3 months post-surgery (Section 3.3.1 and Section 3.3.2).[62,66]

- In THA recipients, mymobility was associated with comparable functional outcomes vs SoC follow-up, with no significant difference in HOOS JR (Hip Disability and Osteoarthritis Outcome Score – Joint Replacement) scores through 1 year post-surgery, SLS times and Timed Up and Go test scores at 1 month post-surgery, and hip flexion at 3 months post-surgery (Section 3.3.3).[65]
- Relative to SoC, mymobility produced comparable QoL outcomes in TKA/PKA recipients through one year of follow-up, and in THA recipients through 3 months of follow-up (the latest timepoint evaluated), as assessed by EQ-5D scores (Section 3.4)[62,65,66]

In secondary analyses of the correlative cohort, tracking patient recovery via both functional and physical activity parameters allowed identification of factors associated with delayed or inadequate recovery (e.g., chronic pre-operative opioid use, shorter post-operative walking sessions, fewer post-operative step counts) (Section 3.3).[67-74] mymobility data also showed notable QoL gains in patients with more limited pre-operative mobility[70,75] and higher baseline comorbidity burden (Section 3.4).[76] Patients reported high satisfaction (>80%) with the platform, with the majority of patients citing reduced surgery-related anxiety and increased preparedness for surgery and recovery.[66] Use of mymobility also enabled significantly higher patient compliance rates with PROM collection, particularly in older patients (≥65 years), compared with traditional data collection and follow-up.[77]

Economic Value: In the RCT cohort, mymobility was associated with a significant decrease in physiotherapy visits compared to standard follow-up for both PKA/TKA patients (Section 3.5.1) and THA patients (Section 3.5.2) ($p<0.001$), with no significant change in unplanned office visits, urgent care visits, or readmissions.[62,65] One-year follow-up data is available for the PKA/TKA cohort, showing a sustained and significant reduction in both physiotherapy visits ($p<0.001$) and ER visits ($p=0.03$) with mymobility vs SoC.[66]

A cost comparison analysis based on data from the TKA/PKA cohort of the mymobility clinical study, performed from the perspective of an integrated healthcare delivery system, estimated significantly decreased costs in the mymobility group (Section 3.6).[78] The decreased HCRU associated with mymobility translated to a significant mean decrease of $720.02 per patient (or $208,328 for the full group, N=452) over 90 days post-surgery, taking into account the cost of the mymobility system ($p=0.001$).[78]

Conclusion: Integration of RTM with mymobility into the treatment pathway for joint arthroplasty may help surgeons address some unmet needs by 1) reducing the need for resource-intensive rehabilitation, as demonstrated by a sustained and significant decrease in physiotherapy visits ($p<0.001$) and ER visits ($p=0.03$) vs traditional care models,[62,65,66] leading to a significant decrease in estimated per-patient costs ($p=0.001$)[78]; 2) facilitating more integrated and effective post-surgical follow-up, as highlighted by significantly higher PROM compliance vs traditional care models ($p<0.0001$)[77]; 3) meeting demand by both patients and providers for digital health services,[66,79] and 4) offering surgeons insights on outcomes and risks via direct and continuous monitoring of patient recovery, including automatic notifications for patients whose gait quality and patient-reported pain management falls below clinician-set thresholds.[50,51]

1 Burden of Illness

1.1 Summary

Summary Points	Section
• Osteoarthritis (OA) is a degenerative and debilitating disease, affecting approximately 51.9 million adults in the US. The most common joints affected by OA are the knee, hip, hands, lower back, and neck.	Section 1.2, Section 1.3
• Joint replacement surgery, which can improve pain and restore mobility to the affected joint, is typically considered in patients who no longer respond to more conservative treatment modalities. ○ Total knee arthroplasty (TKA): is the gold standard treatment for patients with severe knee OA who remain symptomatic following non-surgical treatment ○ Partial knee arthroplasty (PKA): may be used to treat OA affecting a single compartment of the knee by replacing only the damaged part of the joint, while maintaining the healthy components ○ Total hip arthroplasty (THA): is most commonly indicated for pain and stiffness associated with severe OA of the hip that is refractory to other treatments	Section 1.2
• Total joint arthroplasty is among the most common elective procedures in the US. Per NIS data, 5.9 million TKA procedures and 2.8 million THA procedures were performed between 2006 and 2015. ○ The utilization of hip and knee arthroplasty has increased at a rapid pace in recent years, with adults <65 years of age representing the fastest growing demographic ○ Key drivers of increased joint arthroplasty utilization include worsened pain and function scores, radiographic disease progression, and use of intra-articular steroid injections or narcotics	Section 1.3.2; Section 1.3.4
• As utilization of primary joint arthroplasty has increased, particularly at younger ages, utilization of revision surgeries is also expected to increase. ○ Per AJRR data, the total burden of revision knee arthroplasty increased from 8% (2012) to 9% (2021), while the burden of revision hip arthroplasty increased from 10% (2016) to 11% (2021)	Section 1.3.3
• The clinical burden of joint arthroplasty includes both unresolved OA symptoms and potential surgical complications, some of which require readmission and/or revision surgery.‡ ○ Post-TKA complications include, but are not limited to persistent pain, stiffness, instability, and swelling, to surgical site infection, blood loss, and thromboembolism; in two retrospective studies, post-operative complications were reported in 47% to 54% of TKA recipients ○ Post-operative stiffness, often linked to suboptimal rehabilitation, has required MUA in approximately 4% of TKA recipients ○ In a Medicare claims analysis, nearly 8% of THA recipients required readmission within 90 days post-procedure ○ The most common reasons for TKA/THA failure include infection, aseptic loosening, instability, and dislocation (hip)	Section 1.4
• OA is a costly disease: per the BMUS, the total incremental cost associated with OA was $136.8 billion per year between 2008 and 2014, with the largest percentage of OA-related direct medical costs attributable to joint arthroplasty. ○ Published calculations using AHRQ data estimated that TKA and THA were associated with $28.5 billion and $13.7 billion in hospital expenditures, respectively, in 2009	Section 1.5

‡Note that mymobility has not been clinically evaluated to reduce unresolved OA symptoms or surgical complications.

Summary Points	Section
• The economic burden of joint arthroplasty is driven by both hospitalization and post-acute care costs, which have accounted for nearly half of total episode-of-care costs and contribute substantially to variations in payer reimbursement.	Section 1.5.1
• In the year following joint arthroplasty, both payers and patients have continued to incur substantial costs, with the majority attributed to outpatient physiotherapy (>70% of total outpatient costs in one randomized clinical trial).	Section 1.5.1
• Revision surgeries contribute disproportionately to the cost burden of joint arthroplasty, with higher hospital costs and HCRU. ○ The cost burden of revision TKAs is particularly noteworthy, as both LOS (per AJRR data) and total costs (per a claims analysis) were nearly doubled with revision procedures. ○ TKA recipients who undergo MUA require additional HCRU and have a particularly high risk of revision surgery	Section 1.5.2
• Decreasing the patient burden and resource use of traditional physiotherapy remains a key unmet need in patients recovering from joint arthroplasty, particularly as delayed or inadequate post-surgical rehabilitation may further increase HCRU and costs.	Section 1.6.1
• The trend towards reduced LOS following joint arthroplasty highlights the importance of integrated and effective post-surgical follow-up, particularly in younger and more independent patients. ○ Post-arthroplasty LOS has decreased over time (to a mean 1.3 days for TKA and 1.4 days for THA), while home discharge has increased, leaving a potential gap in post-surgical follow-up and support	Section 1.6.1
• Recent surveys have shown that patients increasingly prefer and expect digital engagement in the healthcare setting, but availability of these services has lagged demand. ○ The large majority of patients surveyed (>80%) were amenable to remote monitoring, with higher percentages observed in women and younger patients	Section 1.6.1
• Most critically, improvement in patient outcomes and mitigation of risks remains a key unmet need in joint arthroplasty. ○ Physicians have been found to overestimate improvements in pain and function relative to patients, underscoring the importance of PROMs to inform decision-making ○ When surveyed, patients have reported high rates of dissatisfaction with joint arthroplasty (1 in 5 post TKA, and 1 in 4 younger patients), driven primarily by insufficient functional improvement, inadequate pain relief, and unmet expectations; patients who were less active post-TKA (relative to their pre-surgical baseline) were more likely to be dissatisfied ○ Given that 90% of post-operative recovery takes place outside the purview of healthcare providers, and verification of patient compliance is particularly challenging with traditional care models, connected digital pathways are critical to continuity of care ○ Digital patient engagement following joint arthroplasty has demonstrated significant reductions in both costs and complications[§]; however, these technologies have yet to be widely implemented in clinical practice.	Section 1.6.1, Section 3.7.1

[§]Note that mymobility has not been clinically evaluated to reduce complications.

Summary Points	Section
• Integration of RTM with mymobility into the treatment pathway for joint arthroplasty may help surgeons address some unmet needs: ○ mymobility reduces the need for resource-intensive rehabilitation, as demonstrated by a sustained and significant decrease in physiotherapy visits (p<0.001) and ER visits (p=0.03) vs traditional care models, leading to a significant decrease in estimated per-patient costs (p=0.001) ○ The mymobility platform facilitates more integrated and effective post-surgical follow-up, as highlighted by significantly higher PROM compliance vs traditional care models (p<0.0001) ○ mymobility meets demand by both patients and providers for digital health services, and accordingly, has been associated with high patient satisfaction rates and notable improvements in patient-reported preparedness and surgery-related anxiety ○ mymobility offers surgeons insights on patient outcomes and risks, via direct and continuous monitoring of patient recovery, including automatic notifications for patients whose gait quality and patient-reported pain management falls below clinician-set thresholds	Section 1.6.1

1.2 Clinical Presentation

Osteoarthritis (OA) is a degenerative and debilitating disease, most commonly affecting the joints of the knee, hip, hands, lower back, and neck.[1,2] Patients typically present with chronic joint pain caused by degeneration of the articular cartilage, resulting in loss of function, disability, and reduced quality of life (QoL).[1,2,80]

In addition to pain, other symptoms of OA can include stiffness, swelling, reduced range of motion (ROM), muscle weakness, and joint instability.[2] Due to the progressive nature of the disease, pain intensity and other joint-related symptoms typically worsen over time.[2,80] OA has also been shown to impact outcomes including mental health, sleep, involvement in work and social activities, and even mortality.[80,81]

OA is most commonly diagnosed by physical examination and a review of medical history, based on clinical criteria such as pain, stiffness, and functional limitations.[82,83] Imaging studies (e.g., x-ray, magnetic resonance imaging [MRI]) may be used to identify damage or structural changes to the joint that are consistent with OA, such as loss of joint space, damage to cartilage, osteophyte (bone spurs) formation, subchondral sclerosis (thickening of the bone at the affected joint), and subchondral cysts.[4,82,83]

There is currently no cure for OA and early management of the disease focuses on non-pharmacologic treatment (e.g., patient education and lifestyle changes).[4] Non-pharmacologic therapy for OA may include exercise to strengthen muscles around affected joints, weight loss to reduce excess stress on the joint, and assistive devices such as support braces and walking aids.[2,4] Pharmacologic treatment aims to reduce inflammation and pain caused by OA, including the use of non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroid injections.[2,4]

Joint replacement surgery, which can improve pain and restore mobility to the affected joint, is typically considered in patients who no longer respond to more conservative treatment modalities.[2,4]

- Total knee arthroplasty (TKA): is the gold standard treatment for patients with severe knee OA who remain symptomatic following non-surgical treatment.[4]

- Partial knee arthroplasty (PKA): may be used to treat OA affecting a single compartment of the knee by replacing only the damaged part of the joint, while maintaining the healthy components.[84]
- Total hip arthroplasty (THA): is most commonly indicated for pain and stiffness associated with severe OA of the hip that is refractory to other treatments.[85] For hip OA that has progressed to severe end-stage disease, THA is the gold standard treatment.[5,6]

Additional types of joint arthroplasty used to treat OA include shoulder arthroplasty, which is the third most common joint arthroplasty after knee and hip,[86] and ankle arthroplasty.[87]

1.3 Epidemiology

1.3.1 Epidemiology of Osteoarthritis

OA is the most common form of arthritis and a leading cause of disability in the US.[88] Approximately 51.9 million adults in the US are affected by OA,[3] more than half of whom are working-age adults (18 to 64 years).[88] The prevalence of OA has increased over time, a trend expected to continue given current aging and obesity projections.[89,90]

- The US has the highest age-standardized prevalence rate of OA in the world, at 9,960.88 per 100,000 (as of 2019).[3] Between 1990 and 2019, prevalent cases increased by 79.64%, to 51.87 million; the greatest prevalence increase during this time period was reported for hip OA (115.84% increase), while knee and hand OA increased by 69.55% and 92.80%, respectively.[3]
- An analysis of National Health and Nutrition Examination Survey (NHANES) data (2005 to 2018; N=34,171) examining trends in OA prevalence in US adults, reported a significant linear increase in the age-adjusted prevalence of OA for both men and women ($P_{linear\ trend} \leq 0.0002$).[91]

1.3.1.1 Epidemiology of Knee Osteoarthritis

Per the Burden of Musculoskeletal Diseases in the US (BMUS), 31% of OA physician visits were attributable to OA of the knee as of 2014.[88] Numerous studies have reported increases in the prevalence of knee OA over time,[3,92,93] with the greatest increases observed for those between the ages of 45 and 54 years.[3]

- According to data from the Global Burden of Disease (GBD) study, 24.7 million Americans were affected by knee OA in 2019, with an age-standardized prevalence of 4,705.36 per 100,000.[3,94,95] From 1990 to 2019, the greatest increase in prevalence was reported for the age groups 45 to 49 years (123% increase) and 50 to 54 years (129% increase).[3]
- The Johnston County Osteoarthritis Project, a prospective longitudinal cohort study, reported the point prevalence of symptoms, radiographic knee OA, severe radiographic knee OA, and symptomatic radiographic knee OA at baseline (1999 to 2004; N=2,573) and across three additional time periods: 2006 to 2011 (n=1,595), 2013 to 2015 (n=785), and 2017 to 2018 (n=506).[92] The prevalence of radiographic, severe radiographic, and symptomatic radiographic knee OA increased in the cohort over the four time periods.[92] At the final time point (2017 to 2018), 41% of the cohort had knee symptoms, 61% had radiographic knee OA, 35% had severe radiographic knee OA, and 30% had symptomatic radiographic knee OA.[92]

The prevalence of knee OA increases with age, leading to a 9.3% cumulative risk of developing symptomatic knee OA by the age of 60.[96] Knee OA is a progressive disease, and it is projected that approximately half of all patients will eventually undergo a TKA.[97]

1.3.1.2 Epidemiology of Hip Osteoarthritis

Based on BMUS data, 6% of physician visits for OA were attributable to OA of the hip as of 2014.[88] The incidence of hip OA in the US has increased over the past three decades, with the greatest increases observed in individuals aged 45 to 59 years.[3,98,99]

- In 2019, 5.5 million Americans were affected by hip OA, with an age-standardized prevalence of 1,031.12 per 100,000, according to analysis of GBD study data. From 1990 to 2019, the largest increases in prevalence were reported for age groups 45 to 49 years (126% increase), 50 to 54 years (127% increase), and 50 to 59 years (129% increase).[3]
- Another analysis of GBD study data reported a 112% increase in the incidence of hip OA in the US, from 115,765 incident cases in 1990 to 245,800 incident cases in 2019.[98]
- The Johnston County Osteoarthritis Project reported the point prevalence of symptoms, radiographic hip OA, severe radiographic hip OA, and symptomatic hip OA at baseline (1991 to 1997; N=3,068) and over four additional time periods: 1999 to 2004 (n=2,573), 2006 to 2011 (n=1,595), 2013 to 2015 (n=785), and 2017 to 2018 (n=506). The prevalence of radiographic, symptomatic, and severe radiographic hip OA increased in the cohort over the four time periods. At the final time point (2017 to 2018), 30% of the cohort had hip symptoms, 53% had radiographic hip OA, 9% had severe radiographic hip OA, and 15% had symptomatic hip OA.[99]

The prevalence of hip OA increases with age, resulting in a lifetime risk of ~25%.[99,100] Hip OA is a progressive disease, with pain and functional limitations impairing quality of life (QoL) and eventually exhausting pharmacotherapy options.[89,101]

1.3.2 Utilization of Primary Joint Arthroplasty

Total joint arthroplasty is among the most frequently performed elective procedures in the US.[7]

- According to the 2022 AAOS/AJRR report, over 2.5 million primary and revision hip and knee procedures were reported between 2012 and 2021, representing a 14% increase in procedures from the 2021 report.[8]
- An analysis of Medicare Part B data identified 8.3 million hip and knee arthroplasty procedures between 2000 and 2019, with annual procedures increasing by 100% over the study period.[14]

In addition to knee and hip arthroplasty procedures, which are the most frequently performed, other common surgical sites include the shoulder and ankle (Table 1).

Figure 1: Arthroplasty Procedures in the United States by Surgery Site

	Primary Joint Arthroplasty Utilization	Revision Joint Arthroplasty Utilization
Knee	• 5.9 million TKA procedures from 2006 to 2015 (NIS)[9] • 66,394 PKA procedures from 2012 to 2021 (AAOS-AJRR)[8]	• 465,968 revision procedures from 2006 to 2015 (NIS)[9]

	Primary Joint Arthroplasty Utilization	Revision Joint Arthroplasty Utilization
Hip	• 2.8 million THA procedures from 2006 to 2015 (NIS)[10]	• 400,974 revision procedures from 2006 to 2015 (NIS)[10]
Shoulder	• 104,575 shoulder procedures in 2017 (NIS)[102]	• 10,290 revision procedures in 2017 (NIS)[103]
Ankle	• 5,315 TAA procedures in 2017 (NIS)[104]	• 1,170 revision procedures in 2017 (NIS)[104]

AAOS = American Academy of Orthopaedic Surgeons; AJRR = American Joint Replacement Registry; NIS = National Inpatient Sample; PKA = partial knee arthroplasty; TAA = total ankle arthroplasty; THA = total hip arthroplasty; TKA = total knee arthroplasty

SOURCES: Nham 2023;[9] AAOS 2022;[8] Patel 2023;[10] Shah 2022;[104] Farley 2023.[103]

1.3.2.1 Utilization of Total Knee Arthroplasty

According to the AAOS-AJRR 2022 report, nearly 1.5 million knee arthroplasty procedures were reported between 2012 and 2021, approximately 1.3 million of which were primary TKA procedures.[8]

- The mean age of patients undergoing primary TKA was 67.2 years; patients aged 60 to 69 years accounted for the majority of TKA procedures (38%), followed by patients aged 70 to 79 years and 50 to 59 years (32% and 17%, respectively).[8]
- The majority of patients undergoing TKA were female (61%), and patients with pre-obesity or obesity class I made up 28% and 29% of the patient population, respectively.[8]

A retrospective analysis of NIS discharge data identified 5.9 million TKA procedures and 465,968 revision TKA procedures between 2006 and 2015.[9]

- The mean age of patients who had TKA surgery was 66.3 years.[9]
- The majority of patients who received a primary TKA were female (62.8%) and non-Hispanic white (71.3%).[9]
- Overall, TKA procedures increased by 41.9% from 2006 to 2014.[9]

The estimated prevalence of total knee replacement in the US population in 2010 was 1.52%, according to a study that combined historical incidence data from the National Hospital Discharge Survey (NHDS; 1969 to 1989) and the Healthcare Cost and Utilization Project (HCUP) State Inpatient Database (1990 to 2010).[105] The prevalence of total knee replacement in people aged ≥55 years was 4.55%, and this prevalence increased with age.[105]

The utilization of primary TKA in the US has increased at a rapid pace, with projections estimating continued growth of annual procedures.[7,11-13]

- Analysis of Medicare Part B data (2000 to 2019) reported a 97.1% increase in the annual number of primary TKA procedures, from 156,025 procedures in 2000 to 307,547 procedures in 2019.[14]
- A model based on utilization data from the Centers for Medicare & Medicaid Services (CMS) Medicare/Medicaid Part B National Summary estimated an annual volume increase of 156% for primary TKA procedures in the US, from 188,118 in 2000 to 480,958 in 2019.[13] Regression analysis (assuming exponential growth) predicted an annual growth rate of 4.4% for primary TKA, resulting in a projected 1.2 annual TKA procedures by 2040.[13]
- A 148% increase in annual TKA procedures, from 274,025 in 2000 to 680,150 in 2014, was reported from an analysis of NIS and US Census Bureau data.[7] The incidence of TKA was projected to increase

by 84.9% (to 1.26 million annual procedures) or 147% (to 1.68 million annual procedures) by 2030, according to linear (conservative) or Poisson (exponential growth) models, respectively.[7,12]

- According to another study based on NIS data, regression analysis assuming Poisson distribution estimated that the annual number of primary TKA procedures will increase by 401%, from 1,065,000 in 2020 to a projected 3,416,000 in 2040 in the US.[11]
- An increase in TKA incidence was also reported in a retrospective study that analyzed data from the Humana insurance dataset, including records from more than 22 million patients in the US.[106] The incidence of TKA increased from 114.5 procedures per 100,000 patients in 2007 to 184.8 procedures per 100,000 patients in 2015.[106] Over 11% of procedures were performed on patients <60 years of age and 34.9% of procedures were performed on patients aged 60 to 69 years.[106]

As the utilization of TKA in the US continues to increase, adults <65 years of age represent the fastest growing demographic.[15]

- A US claims analysis reported a significant decrease in the mean age of patients who underwent primary TKA between 2007 and 2016 (from 68.3 years in 2007 to 66.7 years in 2016; p=0.003).[28]
- Based on analysis of data from the NIS, TKA utilization is projected to more than double in patients aged <45 years, from 16,203 procedures in 2020 to 39,027 procedures in 2040; in patients aged 45 to 64 years, TKA procedures are projected to increase from 369,727 in 2020 to 919,433 by 2040.[11]

1.3.2.2 Utilization of Partial Knee Arthroplasty

Based on recent AAOS-AJRR data, PKA accounted for 4.2% of all primary knee arthroplasty procedures in 2021, with 66,394 PKA procedures reported between 2012 and 2021.[8] The mean age of patients undergoing PKA was 64.3 years.[8]

Utilization of PKA has increased in the US since the early 2000s, including in patients <65 years, as age >60 years is no longer considered a selection criteria.[107,108]

- A study analyzing Medicare data (2002 to 2011) and MarketScan commercial data (2004 to 2012) identified 5,235 patients ≥65 years of age (Medicare population) and 23,310 patients <65 years of age (MarketScan population) who had PKA procedures.[108]
    - The rate of PKA utilization increased in the Medicare population (≥65 years) by 49% over 10 years (2002 to 2011) and in the MarketScan cohort (<65 years) by 25% over 8 years (2004 to 2012).[108]
    - The annual increase in the number of PKA procedures averaged 5.8% in the older population and 25.4% in the younger population.[108]
- An analysis of Medicare Part B data reported a 770% increase in the annual number of PKA procedures, from 2,107 procedures in 2000 to 18,301 procedures in 2019.[14]
- A retrospective analysis of the Humana claims database identified 7,684 PKAs that were performed between 2007 and 2016, over which time the annual incidence increased from 4.5% to 12.0%.[109]
- Based on analysis of implant manufacturer data, the annual increase in PKA procedures was 32.5% from 1998 to 2005.[110]

1.3.2.3 Utilization of Total Hip Arthroplasty

According to the AAOS-AJRR 2022 report, over 1 million hip arthroplasty procedures were carried out in the US between 2012 and 2021, with elective primary THA accounting for the majority of hip arthroplasty procedures (N=821,640; 77.2%).[8]

- The mean age of patients undergoing elective primary THA was 65.7 years; patients aged 60-69 years were most highly represented (35%), followed by ages 70 to 79 years and 50 to 59 years (27% and 20%, respectively.[8]
- Women accounted for 55% of the primary THA population overall (the majority of patients over the age of 60 years were female, while the majority of patients aged <60 years were male), and patients with pre-obesity or obesity class I made up 33% and 26% of the population, respectively.[8]

A retrospective analysis of NIS data (2006 to 2015) identified 2.8 million THA patients.[10]

- The average age of patients who had THA surgery was 66.0 years.[10]
- The majority of patients who had primary THA were female (56.4%) and non-Hispanic white (74.8%).[10]

The estimated prevalence of THA in the US population in 2010 was 0.83%, according to the NHDS/HCUP study described above.[105] THA prevalence in people aged ≥55 years was 2.34%, and this percentage continued to increase with age.[105]

The utilization of primary THA in the US has increased at a rapid pace, a trend predicted to continue over the coming decades.[7,10,13,14]

- Based on analysis of Medicare Part B data (2000 to 2019), the annual number of primary THA procedures increased by 113%, from 78,722 procedures in 2000 to 167,916 procedures in 2019.[14]
- The CMS utilization model described above estimated an annual volume increase of 177% for primary THA procedures, from 94,864 in 2000 to 262,369 in 2019.[13] Poisson regression analysis yielded an annual growth rate of 5.2%, resulting in a projection of 719,364 annual THA procedures by 2040.[13]
- According to another study based on NIS data, the annual number of primary THA procedures is projected to increase by 284%, from 498,000 in 2020 to 1,429,000 in 2040 in the US.[11]
- Analysis of data from the NIS and US Census Bureau data (2000 to 2014) reported a 132% increase in annual THA surgeries from 159,856 in 2000 to 370,770 in 2014.[7] The incidence of THA was projected to increase by 71.2% (635,000 annual procedures) or 145% (909,900 annual procedures) by 2030, according to linear or Poisson models, respectively.[7]

Patients aged <65 years have been a key driver of increased THA demand.[16]

- Based on NHDS data, the number of THA procedures among inpatients aged ≥75 years increased by 92% from 2000 to 2010 and increased by 205% for those aged 45 to 54 years.[111]
- According to the NIS, the largest increases in THA incidence between 2000 and 2014 were observed in individuals aged 45 to 54 years and 55 to 64 years, with THA procedures more than doubling in both age groups.[7]

1.3.3 Utilization of Revision Joint Arthroplasty

1.3.3.1 Utilization of Revision Knee Arthroplasty

As utilization of primary TKA procedures has increased (Section 1.3.2.1), particularly in younger patients, the potential for revision surgeries is also projected to increase.[8,17] The largest increase in revision TKA has been reported in patients between 55 and 64 years of age.[8,17]

- According to the 2022 AAOS-AJRR Annual Report, the total burden of revision knee arthroplasty increased from 7.7% in 2012 to 9.2% in 2021.[8] The mean age of patients undergoing revision knee surgery over this time period was 66.4 years.[8]
- Analysis of data from the NIS reported that 465,968 revision TKA procedures were performed from 2006 through the third quarter of 2015, an increase of 28.8% (2006 through 2014).[9]
- An analysis of Medicare Part B data reported a 73.1% increase in annual revision knee arthroplasty procedures from 2000 (9,638 procedures) to 2019 (16,687 procedures).[14]
- Analysis of data from the NIS identified over 70,000 revision TKA procedures performed in 2014, a 102% increase from 2002, with the greatest increase (195%) noted in patients aged 55 to 64 years.[17] From 2014 to 2030, the number of revision TKA surgeries was projected to increase by 78% (to 127,984 procedures) using a linear model, and by 182% (to 202,966 procedures) using a Poisson regression model.[17]
- Patients <65 years of age accounted for 48% of revision TKAs in the US in 2010, projected to increase to nearly two-thirds by the year 2030.[112,113]

Nearly a quarter of primary PKA recipients have undergone revision surgery at 7 years of follow-up.[114]

- Analysis of Medicare (2022 to 2011; N=5,235) and MarketScan (2004 to 2012; N=15,253) data reported that seven years following primary PKA, 19.1% and 25.6% of patients had revision surgery or conversion to TKA in the Medicare and MarketScan cohorts, respectively. With additional follow-up through 10 years in the Medicare cohort, the risk of revision surgery or TKA was 22.8%.[114]

1.3.3.2 Utilization of Revision Hip Arthroplasty

Given increased utilization of primary THA procedures (Section 1.3.2.3), particularly at younger ages, the potential for revision surgeries is also projected to increase.[10,17,18] Across database and registry studies, between 11% and 15% of all THA procedures are revision surgeries.[8,115,116] The utilization of THA revision has increased in patients aged 45 to 65 years, and lifetime risk of a revision THA is highest in younger patients.[18,117]

- According to the 2022 AAOS-AJRR Annual Report, the total burden of revision hip arthroplasty was 10% in 2016 and has remained relatively stable from 2016 to 2021. In this cohort, the mean age of patients undergoing revision hip surgery in the US was 67.4 years of age.[8]
- Per Medicare Part B data, annual revision hip arthroplasties increased by 5.5% from 2000 (18,520 procedures) to 2019 (19,546 procedures).[14]
- Using NIS data from 2012 to 2018, a 28.1% increase in revision THA procedures was reported (from 37,325 to 47,810 annual procedures).[118]
- A 17% increase in annual incidence of THA revision (from 40,237 to 47,075 procedures) was reported for the 6-year period from 2007 to 2013 in an analysis of NIS data (N=320,496).[18] A 41.9% increase in the rate of THA revision surgeries was reported for patients aged 45 to 64 years, driven primarily by a patients aged 55 to 64 years (58.8% increase).[18]

- An analysis of NIS data from 2006 to 2015 identified 400,974 revision THA procedures in the US during this time period.[10] The number of revision THA surgeries increased consistently each year from 2006 to 2014.[10] The average age of patients receiving revision THA procedures was 68.5 years.[10]
- Another analysis of data from the NIS reported that over 50,000 revision THA procedures were performed in 2014.[17] A 36% increase in revision hip arthroplasties was reported from 2002 to 2014, with the greatest increase noted in patients aged 55-64 years of age (184% increase).[17] From 2014 to 2030, the number of revision THA surgeries was projected to increase by 43% using a linear model (to 71,384 procedures), and by 70% using a Poisson regression model (to 85,528 procedures).[17]

1.3.4 Drivers of Increased Arthroplasty Utilization

1.3.4.1 Risk Factors for Osteoarthritis

Risk factors that contribute to the development and progression of OA can be classified as non-modifiable or modifiable risk factors (Table 1).

- The most well-established non-modifiable risk factor for the development of OA is age.[119]
- In the Johnston County study (Section 1.3.1), women were more likely to develop OA compared to men and African Americans were more likely to develop OA compared to white participants.[92,99]
- Obesity is a significant, modifiable risk factor for the development and progression of OA.[119] In the Johnston County study (Section 1.3.1), obese participants were more likely to report symptomatic OA compared to non-obese participants.[92,99]

Table 1: Non-Modifiable and Modifiable Risk Factors for Osteoarthritis

Non-Modifiable Risk Factors	Modifiable Risk Factors
• Age • Sex • Race • Previous injury • Genetics • Joint misalignment	• Obesity • Muscle strength • Occupation • Sporting activities

SOURCE: Gress 2020,[4] OAA 2019[119]

Given that two of the most significant risk factors for OA are age and obesity,[119] the aging US population[120] and the increasing prevalence of obesity in the US[120] will contribute to the increasing prevalence of OA,[89] which will have significant impact on the number of joint arthroplasties performed in the future.

1.3.4.2 Drivers of Joint Arthroplasty Uptake

The early stages of OA can be managed with behavioral and lifestyle modification in addition to oral pharmacologic treatments.[4] However, given the progressive nature of the disease, patients will eventually develop increased pain and functional impairment.[4] Factors correlated with more rapid progression or more severe disease include age, obesity, use of NSAIDs, and not meeting physical activity recommendations.[121,122] For these advanced stages of OA, surgery is the recommended option to restore joint function and reduce pain.[4]

Broadly, key drivers of increased joint arthroplasty utilization by individual patients include worsened pain and function scores, radiographic disease progression, cartilage loss, and use of intra-articular steroid injections or narcotics.[123,124]

- In a nested case-control study of 195 TKA patients and 468 matched controls from the Osteoarthritis Initiative Cohort between February 2004 and October 2015, factors significantly associated with increased utilization of TKA included worsening WOMAC (Western Ontario and McMaster Universities Osteoarthritis Index) scores for pain, function, stiffness, and overall score ($p \leq 0.001$), decreased KOOS scores for pain, symptoms, and QoL ($p<0.001$ for all), global cartilage volume loss >0% ($p=0.010$), medial compartment cartilage volume loss ≥10% ($p=0.027$), lateral compartment cartilage volume loss >0% ($p=0.025$), meniscal extrusion of the medial compartment ($p=0.046$), treatment with narcotics ($p=0.002$), and treatment with intra-articular steroid injections ($p<0.001$).[123]
- In an observational cohort study of patients with OA of the knee (n=186) or hip (n=151) from 2012 to 2014 (mean follow-up of 6.1 years), the factors significantly associated with progression to TKA were grade 3 Kellgren-Lawrence (K-L) radiographic grade ($p<0.01$), grade 4 K-L radiographic grade ($p<0.01$), and Short Form 12 (SF-12) Physical Component Summary (PCS) score ($p<0.05$); factors significantly associated with progression to THA were grade 4 K-L radiographic grade ($p<0.01$), Oxford Hip/Knee Score ($p<0.01$), and SF-12 Mental Component Summary (MCS) score ($p<0.05$).[124]

1.4 Clinical Burden

1.4.1 Clinical Burden of Total Knee Arthroplasty

1.4.1.1 Outcomes

The clinical burden of TKA includes both unresolved OA symptoms and potential surgical complications, some of which require revision surgery. Post-operative complications range from persistent pain, stiffness, instability, and swelling, to surgical site infection, blood loss, and thromboembolism, [19-21] and have been reported to occur in more than half of TKA patients.[20,21]

- In a retrospective cohort study of TKA recipients (n=252; 2010) at the University of Michigan Health System, the most commonly reported adverse event was prolonged pain, which affected nearly one-third of patients. 47% of patients experienced at least one adverse event within 90 days.[20]
- In an Australian registry study of TKA recipients (N=5,662 patients; 2012 to 2018), 53.6% of patients reported complications (14.4% major; 46.6% minor). Minor complications included joint stiffness (18.5%), swelling (15.6%), and paraesthesia (15.6%), while the most common major complications were arthroplasty-related readmission (6.0%) and reoperation (2.5%).[21]
    - Readmissions were due to infections (2.1%), MUA (1.9%), and deep vein thrombosis (0.4%).
    - Reoperations were due to joint stiffness (1.5%) or infection (0.5%).
- Up to 20% of patients report that their knee does not feel “normal” following TKA, which is commonly associated with mid-flexion instability.[19,125]

Stiffness is a common post-operative complication of TKA, often linked to suboptimal rehabilitation, and has required MUA in approximately 4% of TKA recipients.[22-24]

- Based on a retrospective study of the PearlDiver (PearlDiver Inc, Colorado Springs CO) patient record database, including 232,014 patients who underwent TKA in the US between 2010 and 2018, 3.9% of patients required MUA within 1 year.[24]
- Reduced ROM at discharge (total ROM <90°) is an indication for MUA, which improves ROM—particularly if performed early—but function often remains inferior to the general arthroplasty population.[22,126,127]
    - A retrospective cohort analysis of patients who underwent primary TKA in the UK (N=4,581; 1996 to 2005) evaluated the effectiveness of early (<20 weeks; n=56) vs late (>20 weeks; n=30) MUA, finding a significantly higher flexion gain at 1 year post-MUA in the early MUA group vs the late MUA group 1 year (p=0.003).[126]
    - In a Norwegian retrospective study of patients treated with MUA following primary TKA (n=23), total ROM was improved at a mean 2.5 years following MUA (p<0.001), and regression analysis showed a significant correlation between time to MUA and subsequent improvement (i.e., earlier MUA improved outcomes); however, despite improvement in ROM, patients did not achieve normal knee function at follow-up.[22]
- Post-TKA stiffness and MUA are more common in younger patients, with MUA rates over 10% observed in patients <45 years of age.[24,128,129]
    - Based on a retrospective assessment of patients who underwent MUA within 1 year following TKA (N=9,156 patients), MUA rate decreased as age increased, with the highest MUA rate observed in patients aged 40 to 44 years (11%).[24]
    - In a prospective study using data from the Michigan Arthroplasty Registry Collaborative Quality Initiative, among patients who underwent primary TKA (N=3,556; 2014 to 2018), the probability of MUA decreased by 4% for every 1-year increase in age (p<0.001).[129]
    - A retrospective review of the Mayo Clinic Total Joint Registry assessed the risk factors associated with stiffness post-TKA in patients who underwent TKA between 1990 and 2016 (N=12,735); multivariate analysis identified younger age (<65 years) as one of the independent risk factors associated with stiffness post-TKA (p<0.001).[128]

TKA is increasingly performed in the outpatient setting,[84] with comparable outcomes in appropriately selected patient populations; however, outpatient TKA has been associated with an increased risk of peri- and post-operative complications in some studies.[130-132]

- In a retrospective analysis of the NSQIP database, comparing TKA complication rates before and after removal of the procedure from the CMS Inpatient-Only list, no change was observed in rates of 30-day complications, readmission, or reoperation, suggesting that surgeons continued to appropriately select patients who could safely undergo outpatient TKA.[132]
- A retrospective study of data from the Humana subset of the PearlDiver database compared patients who underwent outpatient TKA (n=4,391) and inpatient TKA (n=128,951) between 2007 and 2015. After adjusting for age, sex, and comorbidities, outpatient TKA significantly increased the risk of noninfectious component revision (p=0.039), prosthesis explantation (p=0.013), irrigation and debridement (p<0.001), and stiffness requiring MUA (p<0.001) at 1 year. Additionally, the risk of post-operative deep vein thrombosis (DVT) (within 60 days) and acute renal failure (within 14 days) were higher after outpatient vs inpatient TKA (p<0.001 and p=0.026, respectively).[130]
- A population-based study of patients who underwent TKA between 1997 and 2009 was conducted using data obtained from the Medicare 5% Limited Data Set. Patient data were stratified based on length of stay (LOS): 1 to 2 days (n=7,755), 3 to 4 days standard-stay (n=71,341), ≥5 days (n=23,134),

and outpatient patients (n=454). At 90 days, the outpatient and shorter-stay TKA groups (1 to 2 days) reported less pain and stiffness than the standard stay group. However, the results also showed a correlation between outpatient TKA and increased risk of readmission within 90 days (0.9%); a similar trend was observed with shorter-stay TKA and increased risk of revision (0.4%).[131]

1.4.1.2 Complications Leading to Revisions

As described in Section 1.3.3, approximately 9% of all TKA procedures are revision surgeries,[8] and these procedures have been performed in increasingly younger patients.[8,17]

Based on pooled registry and case series data, primary TKAs have a 25-year survivorship of 82.3%.[133] Revision TKA poses a substantial clinical burden to patients,[8] which is particularly acute in younger, more active patients, who may require multiple revisions over their lifetime due to the survivorship limitations of TKA implants.[113]

- Patients who have TKA at a younger age are at greater risk of revision surgery, according to a retrospective analysis of 4,259 primary TKA patients between 2013 and 2017.[134] The cumulative revision rate at 1 year was 3.4% for patients aged <55 years compared to 1.8% in patients aged 55 years and older (p<0.001).[134] At 5 years, the cumulative revision rate was 5.0% vs. 2.4% for the younger and older age groups, respectively (p<0.001).[134]

The most common reasons for TKA failure include aseptic loosening, instability, and infection.[8,135-137]

- According to the 2022 AAOS-AJRR Annual Report, infection and inflammatory reactions were the most common reasons for knee revision surgery, followed by mechanical loosening and other mechanical complications (28.4%, 24.0%, and 19.4%, respectively).[8] Infection and inflammatory reactions were responsible for 59.3% of early knee revision surgeries (occurring within 3 months of the primary surgery), which were most common in patients aged less than 50 years.[8]
- An analysis of NIS data (2009 to 2016) including more than 450,000 revision TKA procedures reported that the three most common causes of revision TKA surgeries in 2016 were mechanical loosening, other complications of internal joint prostheses, and infections (28.4%, 12.8%, and 12.2%, respectively).[138]

1.4.2 Clinical Burden of Total Hip Arthroplasty

1.4.2.1 Outcomes

THA is an effective treatment for end-stage hip OA, typically producing substantial improvements in pain and function;[139] however, a subset of patients experience suboptimal outcomes and complications (e.g., surgical site infections), some of which require readmission.[25,140,141]

- The rate of surgical site infections ≤90 days post-surgery was 2.1% for primary THA recipients in a retrospective analysis of data from MarketScan and Medicare databases (N=163,547; 2009 to 2015).[141]
- A retrospective study using US Medicare claims (N=288,314; 2012 to 2014) found that the rate of readmissions occurring ≤90 days post-THA was 7.9% across all surgical approaches.[25]

AAOS clinical practice guidelines on the management of hip OA highlight obesity, age, and mental health disorder as risk factors for worse outcomes following THA.[140]

- Obese patients may achieve lower absolute outcome scores vs. non-obese patients, but have a similar level of patient satisfaction and relative improvement in pain and function post-THA (strength of evidence: moderate); obese patients have increased incidence of superficial wound infection, post-operative dislocation, and blood loss post-THA (strength of evidence: limited)
- Increased age is associated with lower functional and QoL outcomes in patients undergoing THA (strength of evidence: moderate); increased age may be associated with higher risk of mortality in patients undergoing THA (strength of evidence: limited); younger age may be associated with higher risk of revision in patients undergoing THA (strength of evidence: limited)
- Depression, anxiety, and psychosis are associated with decreased function, pain relief, and QoL in patients post-THA (strength of evidence: moderate)

1.4.2.2 Complications Leading to Revisions

As described in Section 1.3.3.2, 11% to 15% of all THA procedures are revision surgeries,[8,115,116] and these procedures are being performed in increasingly younger patients.[18,117]

- Patients who undergo THA at a younger age are at greater risk of revision surgery, according to a retrospective analysis of 91,093 elective THA surgeries between 2001 and 2008.[142] For patients who were younger than 55 years, the cumulative incidence of revision at 5 and 15 years of follow up was 3.0% and 5.2%, respectively.[142]

Although US data has shown approximately 95% implant survivorship after 10 years,[143] certain complications of THA (e.g., aseptic loosening, instability, and infection) can necessitate revision surgery.[142]

- According to the 2022 AAOS-AJRR Annual Report, infection and inflammatory reactions were the most common reason for hip revision surgery (21.2%), followed by instability, aseptic loosening, and mechanical complications (18.3%, 16.3%, and 13.8%, respectively).[8] Infection was responsible for 34.0% of early hip revision surgeries, occurring within 3 months of the primary surgery.[8] The majority of hip revision surgeries (50.3%) occurred within three months of the primary surgery.[8]
- According to an analysis of NIS data from 2006 to 2015, (N=400,974 revision THAs), the primary reason for revision surgery was dislocation and instability, which accounted for 21.9% of THA revisions.[10] Mechanical loosening and other mechanical complications were the second and third most common reasons for THA revisions (19.7% and 17.4%, respectively).[10]
- A retrospective chart review conducted on 535 THA revisions from January 2010 to May 2019 reported mechanical failure (36.5%), metallosis (21.4%), dislocation (14.6%), periprosthetic fracture (10.4%), infection (9.9%), and wound complications (3.4%) as major mechanisms of failure that resulted in THA revisions; average time to THA revision was 8.5 years.[144]

Hip dislocation is one of the leading causes of THA revisions, accounting for 15% to 31% of revision procedures across studies.[144-146]

- A study using NIS data to identify all THA revisions performed in the US from 2009 to 2013 (N=258,461 THA revisions) reported that 17.3% of THA revisions were due to dislocations.[145]
- Analysis of data derived from the Swedish Hip Arthroplasty Register of 1,302 THA revisions performed between 2005 and 2010 found that 30.6% of THA revisions were due to dislocations; more than half (69%) of the THA revisions due to dislocations were performed ≤1 year post THA.[146]

1.5 Economic Burden

OA is a costly disease: per the BMUS, the total incremental cost associated with OA was $136.8 billion per year between 2008 and 2014 (most common site was knee followed by hip).[26]

- Incremental direct costs of OA (medical expenditures): $2,018 per person per year
- Indirect costs of OA (earnings losses): $4,274 per person per year

The largest percentage of OA-related direct medical costs are attributable to joint arthroplasty.

1.5.1 Economic Burden of Joint Arthroplasty

Published calculations using Agency for Healthcare Research and Quality (AHRQ) data estimated that TKA and THA were associated with $28.5 billion and $13.7 billion in hospital expenditures, respectively, in 2009.[27]

The economic burden of joint arthroplasty is driven by both hospitalization and post-acute care costs, which have accounted for nearly half of total episode-of-care costs and contribute substantially to variations in payer reimbursement.[28-31]

- TKA: In a retrospective analysis of the Humana claims database, among patients who underwent primary TKA between 2007 and 2016, average post-acute care costs in 2016 totaled $13,498 (42% of total episode-of-care costs).[28] The largest contributors to post-acute care costs were home health ($5,531 per patient), skilled nursing care ($3,248 per patient), and outpatient visits ($1,700 per patient).[28]
- THA: In a Medicare claims study of THA, designed to benchmark 90-day economic outcomes, mean wage-adjusted payments for index hospitalizations were $12,825; additional 90-day post-acute care payments included $2,952 for skilled nursing facility, $2,095 for home health, $965 for inpatient rehab, and $1,269 for readmissions[25]
- Knee and hip arthroplasty: as of FY 2024, CMS reimbursement rates for inpatient hip or knee arthroplasty are $22,166 (with major complication and/or comorbidity) and $13,175 (without major complication or comorbidity);[147] per a Kaiser Family Foundation (KFF) literature review, private insurers typically pay 189% of CMS rates for inpatient hospital services.[148]
- More broadly, an Institute of Medicine report identified post-acute care costs (acute rehabilitation, skilled nursing, home health, outpatient clinic visits) as the largest driver of variability in Medicare spending.[31]

For a primary arthroplasty, formal physiotherapy was shown to account for up to 8% of the episode-of-care costs.[149]

- Based on a claims analysis of patients enrolled in a private insurance plan (n=2,971) or Medicare Advantage (n=1,070) who underwent primary arthroplasty between 2015 and 2017, the highest physiotherapy costs were reported in patients using both home and outpatient physiotherapy ($2,091 and $1,891 for private insurance and Medicare Advantage, respectively, out of total bundle costs of $41,751.75 and $24,686.33)[149]
- In the Virtual Exercise Rehabilitation In-home Therapy (VERITAS) trial, which compared traditional vs home rehabilitation post-TKA, traditional physiotherapy was associated with median 90-day costs of $2,805[30]

In the year following joint arthroplasty, both payers and patients have continued to incur substantial costs, with the majority attributed to outpatient physiotherapy (more than 70% of total outpatient costs in one randomized clinical trial).[32]

- Based on a study evaluating 90-day and 1-year HCRU for patients who underwent TKA between 2013 and 2017 (n=326):[32]
    - In the 90 days following TKA, the mean number of outpatient visits was 27.1, and 77% of these visits were for physiotherapy. Mean total medical costs were $3,720, 84% of which were attributed to outpatient costs.
    - Similar trends were observed in the year following TKA: the mean number of outpatient visits was 48.9, and 70% of these visits were for physiotherapy. The mean total medical costs were $8,930, and of the outpatient costs (60%), 71% were attributed to physiotherapy visits.
- Standard rehabilitation was associated with longer LOS and higher total costs, compared with early initiation of rehabilitation, in a 2016 systematic literature review and meta-analysis of knee and hip arthroplasty.[35]

Performing joint arthroplasty in a hospital outpatient or ambulatory surgical center setting offers a less expensive alternative to inpatient procedures; however, with knee arthroplasty, careful patient selection is required to mitigate increased revision risk.[131,150]

- Hospital outpatient and ambulatory surgical center TKAs were associated with significantly reduced 30- and 90-day costs in a commercial claims database study (n=40,574 TKAs)[150]
    - 30-day mean medical and pharmacy costs were $35,728 (inpatient TKA), $29,154 (hospital outpatient TKA), and $29,945 (ambulatory surgical center TKA) (P-value of analysis of variance: p<0.001)
    - Similar trends were observed for 90-day mean medical and pharmacy costs
- Outpatient and short stay (1 to 2 days) TKAs have produced substantial cost savings vs longer inpatient stays, but with an increased revision risk. Based on results from a population-based study of TKAs performed between 1997 and 2009 (Medicare 5% Limited Data Set), incremental payments for OA-associated costs were $8,527 lower in the outpatient TKA group (n=454) and $1,967 lower with the short stay TKA (n=7,755), relative to the standard stay (3 to 4 days) group (n=71,341).[131]
- Compared to TKA, PKA procedures have been associated with shorter hospital stays and decreased risk of discharge to a rehabilitation facility across studies.
    - In a US retrospective cohort study that matched patients receiving a PKA with patients receiving a TKA, hospital stays were significantly shorter in the PKA group vs the TKA group (1.4 days vs 2.2 days; p=0.0000), and PKA patients were significantly more likely to be discharged on their first post-operative day (71 vs 28 patients; p=0.0000)[151]
    - A US retrospective multicenter study reported that patients undergoing TKA experienced a significantly longer LOS after their procedure (3.3 days vs 2.0 days; p<0.0001) than patients undergoing PKA, and were significantly more likely to be discharged to a rehabilitation facility (18.0% vs 3.1%; p<0.0001)[152]
    - A US retrospective review comparing primary PKA and TKA procedures performed by a single surgeon also found a shorter length of stay in the PKA group (2.2 ± 1.1 vs 3.8 ± 2.4; p<0.001), with 4% of PKA patients discharged to a rehabilitation facility vs 25% of TKA patients[153]

Outpatient THA was more cost effective than inpatient THA in a US-based cost-effectiveness model,[154] and has been associated with comparable functional outcomes, complications, and readmissions.[155-157]

- Based on multivariable analysis of data from patients undergoing THA (N=112), pre-operative pain level and patient expectations were the primary drivers of LOS (p=0.001 and p<0.001, respectively),[158] highlighting the need for improved patient engagement and the potential value of remote patient monitoring.[158,159]

1.5.2 Economic Burden of Revision Surgery

Revision surgeries contribute disproportionately to the cost burden of joint arthroplasty, with higher hospital costs and healthcare resource use (HCRU).[33,34] The cost burden of revision TKAs is particularly noteworthy, as both LOS (per AJRR data) and total costs (per a claims analysis) were nearly doubled with revision procedures.[33,34]

- A US retrospective study of patients who underwent TKA between 2007 and 2009 (n=2,383) found that mean 90-day healthcare costs were $40,782 for revision TKA vs $22,194 for primary TKA.[33]
- An assessment of NIS data from 2005 to 2010 (N=301,718 revisions) found that patients undergoing revision TKA required a mean (SD) LOS of 4.8 days (10.5) and a mean (SD) hospitalization cost of $23,130 ($36,643);[116] in a more recent study of NIS data (2009 to 2013; 337,597 revisions), the mean LOS for revision TKA had decreased to 4.5 days, while the mean total charges had increased to $75,028.[160]
- Per the AAOS-AJRR 2022 annual report, while LOS for overall TKA has decreased over the last decade, LOS following revision TKA has stayed relatively steady (from mean 3.7 days in 2012 to 3.5 days in 2021).[34]
- The cost burden of revision TKA is particularly high in older patients: a US single-center study of patients who underwent revision TKA between 2018 and 2020 characterized factors that contribute to hospital costs in patients aged 60 to 69 (n=158), 70 to 79 (n=94), and ≥80 (n=24), reporting that older patients undergoing revision TKA are more likely to require a longer stay (p<0.0001), inpatient rehabilitation, and/or discharge to a skilled nursing facility.[161]
    - LOS: 2.8 days (60 to 69 years of age), 3.4 days (70 to 79 years of age), 3.8 (≥80 years of age)
    - Inpatient rehabilitation: 1.9% of patients aged 60 to 69 years, 8.5% of patients aged 70 to 79 years, 8.3% of patients aged ≥80 years
    - Discharge to a skilled nursing facility: 12.6% of patients aged 60 to 69 years, 27.7% of patients aged 70 to 79 years, 75% of patients aged ≥80 years

In the US, the annual economic burden of TKA revision has been estimated at $2.7 billion in hospital charges alone, and predicted to exceed $13 billion by 2030.[112] While Medicare is the primary payer for the majority of revision TKAs (59.5% per NIS data), private payers account for 30.9%.[162]

TKA recipients who undergo MUA, a procedure often linked to suboptimal rehabilitation, require additional HCRU and have a particularly high risk of revision surgery.[22-24]

- MUA is a painful and costly procedure often requiring general anesthesia, followed by 2 to 3 days in the hospital on a continuous passive motion machine[22]
- Patients who undergo MUA have nearly triple the risk of requiring a revision TKA:

- Sambandam et al. 2002 reported that patients who received MUA ≤1 year following TKA were 2.9 times more likely to undergo revision TKA at 2 years of follow up (p<0.05), based on comparison of the MUA cohort (n=538) with the matched non-MUA cohort (n=194).[24]
- In a retrospective study of data from the American Joint Replacement Registry (2012 to 2019), among patients ≥65 years of age who underwent a MUA following primary TKA (N=3,918), 3.4% of patients required a revision after a median 9 months.[163]
- A retrospective analysis of US registry data from patients who underwent primary TKA between 2003 and 2007 (N=2,790) demonstrated that additional MUAs significantly increased the risk of revision surgery (relative risk of 9.7 after 2 MUAs and 27.02 after ≥3 MUAs; p<0.001 for both) at a mean follow-up of 9.7 years, and significantly decreased survivorship (89.4% vs 97.2% for MUA and non-MUA, respectively; p<0.001).[62]

Revision THAs are also significantly more expensive than primary THAs, particularly revisions due to dislocation.[164-166]

- In a retrospective analysis from NYU Langone, revision THA was associated with significantly higher hospital operating direct cost (29.2% greater), hospital operating total cost (28.8% greater), direct hospital cost (24.7% greater), and total hospital cost (26.4% greater) (p<0.05).[164]
- In a retrospective study from Duke University, revision THA was approximately 19% more costly than primary THA, including significantly greater direct costs, nursing services, surgery services, and medical/surgical supply costs (p<0.05).[165]
- A Mayo Clinic study of patients who experienced a dislocation following primary THA (N=99) reported that 37% of patients required subsequent revision surgery, with average hospital costs per patient (for ≥1 closed reduction and subsequent revision THA) that were 148% higher than an uncomplicated primary THA.[166]

Incidence of THA revision has increased in patients between 45 and 65 years of age, and lifetime risk of a revision THA is highest in younger patients.[117,167]

- A retrospective study using NIS data to identify all THA revisions from 2007 to 2013 (n=320,496 THA revisions) reported a 41.9% increase in the incidence of THA revision in patients between 45 and 64 years of age, adjusted for population growth; a greater increase was reported in the 55 to 64 years old age group (58.8%) vs. the 45 to 54 years old age group (17.4%).[167]

Statistical projections based on NIS data predict a 137% increase in the total number of THA revisions in the US by 2030 (from 40,800 in 2005 to 96,700 in 2030).[168]

1.6 Unmet Need

1.6.1 Description of Unmet Need

1.6.1.1 Need for less burdensome and resource-intensive rehabilitation

Decreasing the patient burden and resource use of traditional physiotherapy remains a key unmet need in patients recovering from joint arthroplasty. As described in Section 1.5, traditional physiotherapy is a key driver of post-acute care costs following joint arthroplasty; based on the results of one randomized clinical trial, traditional physiotherapy accounted for over 70% of outpatient costs requiring an average of 34 outpatient visits in the year following TKA.[32] The burden of in-person physiotherapy impacts both

patients and caregivers, as traditional outpatient rehabilitation includes 6 weeks of clinic-based appointments, and patients are typically not permitted to drive for 6 weeks post-surgery.[29]

Beyond joint arthroplasty, physiotherapy represents a significant contributor to post-acute care costs across a broad range of orthopedic surgeries, including total shoulder arthroplasty,[169] total ankle arthroplasty,[170] and rotator cuff repair.[171]

Delayed or inadequate post-surgical rehabilitation may further increase HCRU and costs; a 2016 systematic literature review and meta-analysis of knee and hip arthroplasty noted longer LOS and higher total costs with standard rehabilitation (commencing on either post-operative day one or post-operative day two) compared to earlier initiation of rehabilitation (commencing on the day of surgery or post-operative day one).[35]

1.6.1.2 Need for more integrated and effective post-surgical follow-up

The trend towards reduced LOS following joint arthroplasty highlights the importance of integrated and effective post-surgical follow-up, particularly in younger and more independent patients.[29,36] In TKA recipients, LOS has decreased steadily over time (to a mean 1.3 days), while home discharge has increased, leaving a potential gap in post-surgical follow-up and support.[34,36-38]

- A US retrospective study of the National Surgical Quality Improvement Program (NSQIP) assessed the overall LOS trend in patients who underwent TKA between 2006 and 2016 (N=221,764). Patient data was stratified into 3 cohorts (2006 to 2009, 2010 to 2013, and 2014 to 2016) based on the year of primary TKA. Multivariate analysis demonstrated a significant decrease in LOS ($p<0.001$) between 2006 and 2016, which was primarily attributed to rapid recovery protocols; shorter LOS was particularly prevalent in younger, healthier, and more functionally independent patients.[36]
    - Mean LOS: 3.7 days (2006-2009), 3.3 days (2010-2013), 3.0 days (2014-2016)
- Based on the AAOS-AJRR 2022 annual report (N=805,296 knee arthroplasties), mean LOS following TKA decreased from 2.9 days in 2012 to 1.3 days in 2021.[34] Likewise, mean LOS following PKA decreased from 2.3 days in 2012 to 0.6 days in 2021.[34]
- The proportion of TKA recipients discharged to home increased to 92.9% as of 2021 (up from 85.2% in 2017), while the proportion of patients discharged to skilled nursing facilities decreased from 12.7% in 2017 to 5.6% in 2021.[34]
- Outpatient surgeries accounted for the majority of PKA procedures as of 2016: based on a retrospective study of a national claims database, utilization of outpatient PKA increased significantly between 2007 and 2016 (14.5% to 58.1%, $p<0.001$).[109]
- When surveyed, patients have shown a preference for shorter LOS following knee arthroplasty; however, remaining doubts and concerns related to early discharge underscore the need for ongoing support.[37]

Mean LOS following primary THA has also decreased (to 1.4 days in 2021),[34] while the number of THA procedures being performed in the outpatient setting has increased.[155] As observed with knee arthroplasty, the large majority of THA recipients are discharged to home.[34]

- Based on the AAOS-AJRR 2022 annual report (N= 537,686 hip arthroplasties), mean LOS following primary elective THA decreased from 3.0 days in 2012 to 1.4 days in 2021.[34] As of 2021, 92.0% of patients were discharged to home (up from 87.6% in 2017), while discharges to skilled nursing facilities decreased to 6.2% (down from 10.8% in 2017).[34]

- Outpatient discharges were noted for 2.9% of THA procedures in a retrospective analysis of the US Humana PearlDiver database (N=75,780; 2007 to 2016), with overall incidence rates of 10.5 per 100,000 for outpatient THA and 352.3 per 100,000 for inpatient THA.[155] The incidence of outpatient THA procedures increased from 2.0 per 100,000 in 2007 to 4.0 per 100,000 in 2015, although the relative incidence of outpatient vs. inpatient procedures did not significantly change.[155]

1.6.1.3 Patient and provider demand for digital health services

Recent surveys have shown that patients increasingly prefer and expect digital engagement in the healthcare setting, a trend accelerated by the COVID-19 pandemic.[39-42] However, although high patient demand exists for digital healthcare (e.g., digital communication with their provider, monitoring their condition via an app), availability of these services has lagged demand.[39,40] The results of the 2020 Healthcare Consumer Study (N=1,502 respondents, primarily aged 18 to 54) indicated that the majority of patients prefer to interact through a patient portal, prefer online appointment scheduling, and would consider switching physicians if they lack digital services.[39] When arthroplasty patients were surveyed to gauge their comfort with remote monitoring (N=293), 83.6% of patients were willing to wear a remote monitoring device, and 84.3% of patients were comfortable having their activity data collected, with higher percentages observed in women and younger patients.[172]

The COVID-19 pandemic has further highlighted the demand and necessity for remote patient monitoring, accelerating the shift towards digital care pathways and digital health tools.[41,42] Use of and demand for Patient Engagement Platforms (PEPs) have grown during the pandemic, a trend expected to continue post-pandemic.[42] PEPs enable remote patient monitoring and telemedicine, and also provide educational resources, at-home therapeutic alternatives, proactive and effective patient communication, and meaningful connections between patients and providers.[42] Additionally, PEPs enable rapid wound assessment via image sharing, which can lead to proactive treatment modifications.[42] Specifically in joint arthroplasty, the pandemic also accelerated an existing shift towards outpatient procedures, which require more robust and structured follow-up.[41]

Notably, remote surgery preparation has been linked to shorter LOS[**]; in a US prospective study of patients who underwent primary TKA between 2015 and 2017 (N=476), patients who utilized telephone-based surgery preparation had a significantly shorter post-operative LOS (mean LOS: 2.0 days) vs patients who received standard surgery preparation (mean LOS: 2.7 days; $p<0.001$).[38]

1.6.1.4 Potential to improve patient outcomes and mitigate risks

Effective digital care pathways have reportedly improved patient experiences and impacted outcomes that matter to patients[††] (e.g., earlier discharge, recovery in the home setting, and earlier return to usual activity levels).[39,40,173,174] An estimated 1 in 5 patients reported dissatisfaction with their TKA procedure, driven by both suboptimal clinical outcomes and poor alignment of outcomes with expectations,[44,45] and even higher dissatisfaction rates (1 in 4) were reported in younger TKA recipients (<55 years of age).[46] Key drivers of TKA dissatisfaction included the degree of improvement in function, degree of pain relief

[**] Note that mymobility has not been clinically evaluated to reduce LOS.

[††]Note that mymobility was not utilized in these studies.

following surgery, and unmet expectations.[44] Notably, patients who were less active post-TKA were more likely to be dissatisfied.[44] Physical parameters contributing to post-operative patient satisfaction included ROM and gait parameters (e.g., walking speed and flexion).[43,175]

Additionally, given that 90% of post-operative recovery takes place outside the purview of healthcare providers, connected digital pathways are critical to continuity of care.[47] Verification of patient compliance, for example, is challenging with traditional care models, which typically rely on self-reported diaries.[29] In contrast, remote monitoring devices offer more holistic objective and subjective assessments of both patient progress (e.g., knee flexion/extension) and patient compliance.[29]

Integration of patient-generated data throughout the care pathway is critical to improving patient outcomes, but gathering such data has been done in only a limited and investigational capacity.[37,43,176,177]

- Physicians have been found to overestimate pain and function improvements relative to patients.[43] In a retrospective study of 375 patients who underwent primary TKA between 2000 and 2009, results of the 2011 Knee Society Scoring System found that:[43]
    - Patient-derived function scores correlated weakly with physician-derived scores
    - Patient-derived symptoms scores correlated poorly with physician-derived scores
- Patient-reported outcome measures (PROMs) are important measures that can be used to inform shared decision-making, bridging the gap between which outcomes are considered important to surgeons vs patient;[177] however, measurement of patient experience across the care pathway requires further standardization and validation.[37]

Digital patient engagement following joint arthroplasty has demonstrated significant reductions in both costs and complications; in a multicenter observational claims analysis, 186 patients who underwent knee or hip arthroplasty were enrolled in an automated digital care plan (consisting of scheduled guidance and telemonitoring questions spanning 30 days pre-surgery to 90 days post-surgery) and compared to 372 patients who had undergone the same procedures with the same physicians prior to platform implementation.[48] Patients in the digital care platform group had a significant decrease in potentially avoidable 90-day costs (mean savings of $656.52/patient; p=0.006), a numerical decrease in 90-day hospital readmissions (45.5% relative reduction), and a significant decrease in 90-day complications (54.5% relative reduction; p=0.004).[48‡‡]

Remote activity monitoring paired with bidirectional text messaging has also shown the potential to reduce readmissions following joint arthroplasty. In a randomized clinical trial of knee and hip arthroplasty recipients (N=242), the remote monitoring arm had a significant decrease in rehospitalization rate (3.4% vs 12.2%; p=0.01) as well as a significant decrease in mean hospitalizations (4.2 vs 13.0; p=0.02) vs the usual care arm.[49]

However, while remote monitoring and patient engagement have shown the potential to reduce costs, HCRU, and complications following joint arthroplasty,[48,49] these technologies have yet to be widely implemented in clinical practice.

‡‡Note that mymobility has not been clinically proven to reduce LOS or complications.

1.6.2 How the New Technology Addresses the Unmet Need

In recognition of the evolving landscape of digital medicine, CMS recently adopted Current Procedural Technology (CPT) codes for two types of remote monitoring:[178,179]

- Remote patient monitoring (RPM): digital technology used to monitor and automatically capture objective physiologic data; codes are condition agnostic, but most commonly used for chronic disease (e.g., hypertension, diabetes)
- Remote therapeutic monitoring (RTM): digital technology used to monitor and collect data on therapeutic response, including self-reported data; indications are limited to musculoskeletal, respiratory, and therapy response/adherence

Following addition of RPM codes to the CMS-reimbursed code set in 2019, substantial growth in utilization of these codes has been observed.[178] Parallel codes for RTM, effective as of January 2022, were subsequently introduced to allow adoption of innovative digital technologies such as mymobility®.[178]

Integration of RTM with mymobility into the treatment pathway for joint arthroplasty may help surgeons address some unmet needs:

- mymobility reduces the need for resource-intensive rehabilitation, as demonstrated by a sustained and significant decrease in physiotherapy visits ($p<0.001$) and ER visits ($p=0.03$) vs traditional care models (Section 3.5), leading to a significant decrease in estimated per-patient costs ($p=0.001$) (Section 3.6).
- The mymobility platform facilitates more integrated and effective post-surgical follow-up, as highlighted by significantly higher PROM compliance vs traditional care models ($p<0.0001$) (Section 3.4.4).
- mymobility meets demand by both patients and providers for digital health services, and accordingly, has been associated with high patient satisfaction rates and notable improvements in patient-reported preparedness and surgery-related anxiety (Section 3.4).
- Finally, mymobility offers surgeons insights on outcomes and risks, via direct and continuous monitoring of patient recovery, including automatic notifications for patients whose gait quality and patient-reported pain management falls below clinician-set thresholds (Section 2.2).

While RCT evidence supporting the value of mymobility is currently available only for knee and hip arthroplasty,[62,65,66] the mymobility platform has been developed to support a wide variety of orthopedic procedures, including shoulder and ankle arthroplasty, rotator cuff repair, and cervical and lumbar fusion procedures (see Table 2 for a complete list of available care plans).[53]

In addition to mymobility, several other platforms have been developed to provide RTM in orthopedic surgery, including MotionSense® with OrthoLogIQ® (Stryker; Kalamazoo, MI), and the Force Therapeutics digital care platform (Force Therapeutics; New York, NY), while the MedBridge GO app (Medbridge; Bellevue, WA) provides RTM for home exercise rehabilitation in the broader physical therapy space. However, a targeted literature review did not identify published clinical trial data for these products.

2 Product Information

2.1 Summary

Summary Points	Section
• mymobility is a care management platform that connects patients receiving surgical procedures with their care team via smartphone and/or Apple Watch (for iOS users), guiding and engaging patients throughout the episode of care and providing clinicians with continuous data and patient-reported feedback. ○ Pre-procedure, mymobility offers patient education, individualized exercises, and direct engagement with the care team to help patients prepare for surgery. ○ Post-procedure, mymobility tracks both patient-reported outcomes and passively collected metrics, allowing clinicians to continuously monitor patient recovery (and set automatic exceptions for patients who fall below set threshold for gait quality and pain management), and provide self-directed in-app exercises to replace or supplement in-person physical therapy	Section 2.2
• By facilitating patient engagement and data collection, mymobility is intended to increase patient compliance, enable clinical insights, and increase the efficiency of the care team.	Section 2.2
• mymobility includes 3 patient-facing options (an iOS patient mobile application, to be used with or without Apple Watch, an Android mobile application, and a web-based application), as well as 3 clinician-facing options (an iOS mobile application, an Android mobile application, and a web-based application).[180]	Section 2.5
• mymobility integrates seamlessly into ZBEdge Dynamic Intelligence, a connected suite of digital and robotic technologies (WalkAI Artificial Intelligence[§§], OrthoIntel Orthopedic Intelligence Platform, ROSA Robotics System, and Persona IQ The Smart Knee) designed to deliver data-driven clinical insights across the continuum of patient care, unlocking the full potential of Zimmer Biomet's cutting edge digital technologies, robotics, and implant solutions ○ Supplementing the mymobility care pathway with other technologies within ZBEdge can facilitate collection of additional data, enhance care delivery via digital and robotic technologies, and further personalize the experience to optimize patient engagement.	Section 2.2.1
• The mymobility care management software platform is cleared as a medical device by the FDA and fits the requirements of an RTM device. Physicians and other qualified healthcare personnel may bill for mymobility using the CPT codes for RTM services to monitor the musculoskeletal system.[***]	Section 2.3 and Section 2.4

2.2 Description of mymobility

mymobility is a care management platform that connects patients undergoing surgical procedures with their care team via smartphone and/or Apple Watch (for iOS users).[50] The mymobility platform is designed to guide and engage patients, while providing clinicians with continuous data and patient-reported feedback to help surgeons optimize patient care, outcomes, and satisfaction (Figure 2).[50,51] mymobility supports patients and clinicians through the entire episode of care, from pre-surgical education through post-surgical recovery:

[§§]WalkAI is available for patients undergoing a hip or knee replacement using the mymobility app on an iPhone 8 or higher supported by the current or previous version of iOS.

[***]Separate billing for RTM is not permissible for physicians receiving a global payment for the episode of care.

- Before the procedure, mymobility provides procedural education in a patient-friendly format, including answers to commonly asked questions, exercises based on an individual treatment protocol, as well as direct engagement with the surgical and care teams through encrypted messaging and video; these features are intended to support patient engagement and to help patients prepare for surgery.[50,51]
- After the procedure, the mymobility app offers further support and engagement during recovery, including telemedicine follow-up video visits, monitoring tools, and joint/Quality of Life (QoL) patient-reported outcome measures (PROMs) (e.g., HOOS/KOOS, HOOS JR/KOOS JR, PROMIS-10, and/or VR-12, with additional PROMs available depending on the procedure type and mymobility plan).[50,53] Self-directed in-app video exercises may also be provided to qualified patients to replace or supplement supervised physical therapy visits post-surgery.[51]

By facilitating patient engagement and data collection, mymobility is intended to increase patient compliance, enable clinical insights, and increase the efficiency of the care team.[50]

Figure 2: Overview of the Capabilities of mymobility

Source: Zimmer Biomet 2023 mymobility Product Webpage.[51]

In addition to patient engagement and self-reported data, mymobility allows the clinician and their care team to directly and continuously monitor patient recovery—based on various passive RTM metrics—via their smartphone and through optional integration with the Apple Watch (Table 2).[51] The RTM and PROM data collected by mymobility can be analyzed through the clinician dashboard, and can optionally be integrated into the OrthoIntel Interactive Reports (see Section 2.2.1 for more details about the OrthoIntel Orthopedic Intelligence Platform).[50,53] Care teams can set automatic exceptions for patients who fall below set thresholds for gait quality and patient-reported pain management, with the goal of reducing variability in patient outcomes.[50] mymobility also features enhanced Electronic Health Record (EHR) integration and automated enrollment from surgical scheduling, to maximize operational efficiency.[50]

CMS requirements for RTM, described in more detail in the procedure coding section below (Section 2.4), can also be found on the CMS website.

Table 2: RTM Metrics Available for mymobility

Mobility/Functional and Gait Quality Data	Engagement Data	Heart Rate and Other Data
• Patient steps • Flight of stairs climbed • Stand hours • Exercise completion • Shoulder range of motion[a] • Gait speed • Double support percentage • Step length[b] • Speed ascending/descending stairs[b] • Gait asymmetry[b]	• Exercise adherence • PROM adherence • Education adherence • Patient-reported pain management tracking[c] • Patient-reported narcotic/non-narcotic tracking[c]	• Average resting heart rate • Average walking heart rate • Heart rate variability • VO_2 max[b] • Falls detection[b] • Sleep[b]

PROM = patient-reported outcome measure; RTM = remote therapeutic monitoring; VO_2 = maximal oxygen consumption.

[a] Available to iPhone 10 or higher users (using iOS 14 or newer) or Android users with ARCore™

[b] Data available separately upon request

[c] Collected via patient-reported data as time check-in surveys using the mymobility app

Source: Zimmer Biomet 2023 mymobility Product Webpage.[51]

2.2.1 Integration with ZBEdge Dynamic Intelligence

mymobility integrates seamlessly into ZBEdge Dynamic Intelligence, a connected suite of digital and robotic technologies (WalkAI Artificial Intelligence[†††], OrthoIntel Orthopedic Intelligence Platform, ROSA Robotics System, and Persona IQ The Smart Knee) designed to deliver data-driven clinical insights across the continuum of patient care, unlocking the full potential of Zimmer Biomet's cutting edge digital technologies, robotics and implant solutions (Figure 3).[58-61] Supplementing the mymobility care pathway with other technologies within ZBEdge can facilitate collection of additional objective data throughout the patient journey, enhance delivery of care by connecting digital and robotic technologies, and personalize the experience to optimize clinician and patient engagement.[58]

- The WalkAI™ Artificial Intelligence Model uses anonymized ZBEdge data and a patient's personal recovery metrics via mymobility to predict 90-day post-operative gait speeds, and notify providers of outlier cases relative to other similar patients.[51]
- OrthoIntel Orthopedic Intelligence Platform provides interactive and customizable reports for the data collected in the ZBEdge suite, allowing providers to explore the direct impact of pre-operative, intraoperative, and post-operative data on treatment outcomes.[58]
- The ROSA Robotics System is designed to enhance the accuracy and reproducibility of joint arthroplasty procedures by assisting with pre-operative preparation, bone resection, and intra-operative positioning of implant components.[181-185] (For more information about the ROSA Robotics System, please refer to the Value Analysis Briefs for ROSA Knee, ROSA Partial Knee, and ROSA Hip, available upon request)

[†††] WalkAI is available for patients undergoing a hip or knee replacement using the mymobility app on an iPhone 8 or higher supported by the current or previous version of iOS.

Figure 3: The ZBEdge Dynamic Intelligence Suite

2.3 Approval Status and Classification

The mymobility care management software platform is cleared as a class I medical device by the FDA, under Code of Federal Regulations (CFR) number 888.1520 (product code KQW; Nonpowered goniometer).[54,55] For CMS classification, mymobility fits the requirements of an RTM device by collecting musculoskeletal system status, treatment adherence, and treatment response through direct measures as well as self-reported metrics (as opposed to general physiologic data covered by the RPM classification).[57,186]

2.4 Procedure Codes

Physicians and other qualified healthcare personnel may bill for mymobility using the following Current Procedural Technology (CPT) codes for RTM services (Table 3).[57,186]

Table 3: CPT Codes Relevant to mymobility‡‡‡

CPT Code	Description	2024 Calendar Year Medicare Non-Facility Allowable Fee Schedule
RTM[a,b]		
98975[c,d]	Remote therapeutic monitoring (e.g., therapy adherence, therapy response); initial set-up and patient education on use of equipment	$20
98977[c]	Remote therapeutic monitoring (e.g., therapy adherence, therapy response); device(s) supply with scheduled (e.g., daily) recording(s) and/or programmed alert(s) transmission to monitor musculoskeletal system, each 30 days	$47

‡‡‡ Disclaimer: Providers, not Zimmer Biomet, are solely responsible for ensuring compliance with Medicare, Medicaid and all other third-party payer requirements, as well as accurate coding, documentation, and medical necessity for the services provided. Before filing claims, providers should confirm individual payer requirements and coverage/medical policies. The information provided in this reference is not legal or coding advice; it is general reimbursement information for reference purposes only. It is important to note that Zimmer Biomet provides information obtained from third party authoritative sources and such sources are subject to change without notice, including as a result in changes in reimbursement laws, regulations, rules and policies. This information may not be all-inclusive and changes may have occurred subsequent to publication of this reference. This document represents no promise or guarantee by Zimmer Biomet regarding coverage or payment for products or procedures by Medicare or other payers. Inquiries can be directed to the provider's respective Medicare Administrative Contractor, or to appropriate payers. Zimmer Biomet specifically disclaims liability or responsibility for the results or consequences of any actions taken in reliance on information in this guide.

CPT Code	Description	2024 Calendar Year Medicare Non-Facility Allowable Fee Schedule
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes	$50
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)	$39

CPT = Current Procedural Terminology; FDA = Food and Drug Administration; RPM = remote physiologic monitoring; RTM = remote therapeutic monitoring.

[a] Only one practitioner may bill for RTM (or RPM, but not both) during a 30-day period, and only when ≥16 days of data have been collected on at least one medical device.

[b] Note that surgeons billing for a global episode cannot bill separately for RTM services during the global pay period.

[c] RTM device must be defined as a medical device per the FDA.

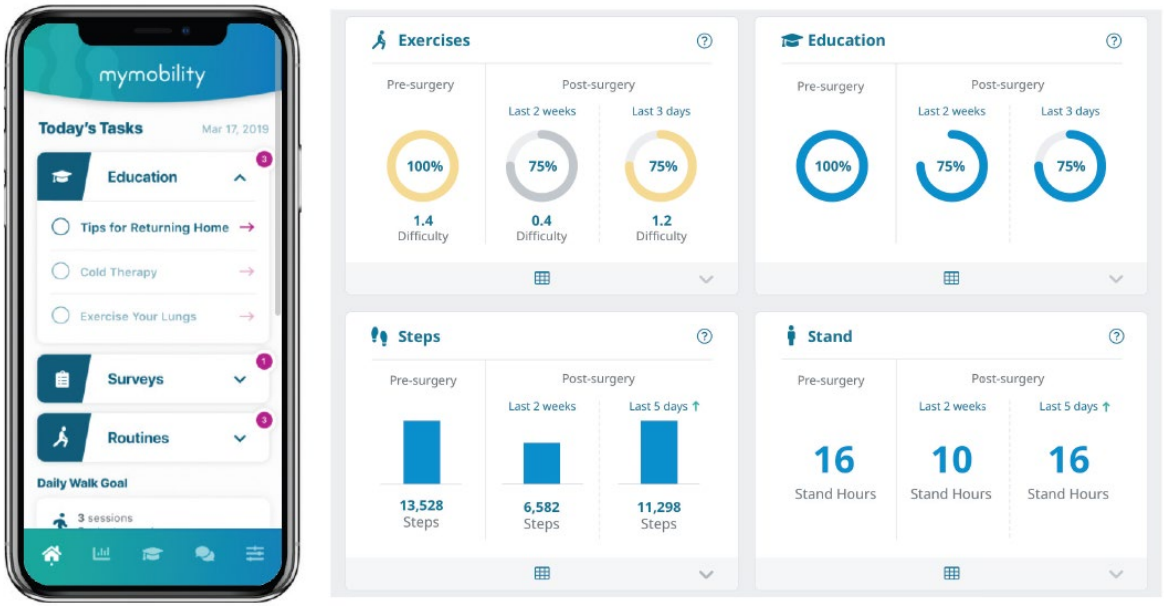
[d] RTM device must monitor ≥16 days of data per each 30-day period in total.

Source: Calendar Year 2024 Medicare Physician Fee Schedule, Final Rule[57]; Zimmer Biomet Coding Reference Guide[186]

2.5 Components and Specifications

mymobility includes 3 patient-facing options (an iOS patient mobile application, to be used with or without Apple Watch, an Android mobile application, and a web-based application), as well as 3 clinician-facing options (an iOS mobile application, an Android mobile application, and a web-based application); sample images from the patient smartphone app and clinician web portal are shown in Figure 4.[180]

Figure 4: Sample Image from the mymobility Patient Smartphone App and Physician Web Portal



Source: Crawford et al, 2021.[65]

In addition to PKA, TKA, and THA, mymobility can support a variety of orthopedic procedures, including shoulder arthroplasty, total ankle arthroplasty, sports protocols, and spine procedures (Table 5).[53] (Note: mymobility has not been evaluated for clinical or economic outcomes outside of PKA/TKA/THA, see Section 3 for a summary of existing clinical and economic evidence

Table 4: Available Care Plans for mymobility

Available Care Plans	
• Knee Arthroplasty ○ Total Knee[a] ○ Partial Knee[a] ○ Revision Knee[b] • Hip Arthroplasty ○ Total Hip[a] ○ Revision Hip[b] • Shoulder Arthroplasty[b] ○ Total Shoulder ○ Reverse Total Shoulder ○ Rotator Cuff Repair ○ Shoulder Instability • Hip Fracture[b] ○ Hip ORIF Cannulated Screws ○ Hip ORIF IM Nail ○ Hemiarthroplasty ○ Total Hip arthroplasty	• Ankle Arthroplasty[b] ○ Total Ankle ○ Deformities of the Fore, Mid, and Hind Foot • Sports Procedures[b] ○ ACL Repair ○ Meniscal Repair ○ Meniscectomy ○ Rotator Cuff Repair ○ Shoulder Instability ○ Hip Arthroscopy • Spine Procedures[b] ○ Cervical Disc Arthroplasty ○ Cervical Fusion/Non-Fusion ○ Lumbar Fusion/Non-Fusion

ACL = anterior cruciate ligament; HSS = Hospital for Special Surgery; IM = intramedullary; ORIF = open reduction and internal fixation.

[a] Dedicated HSS[§§§] care plans are also available for these procedures

[b] mymobility has not been evaluated for clinical or economic outcomes in these settings

Source: Zimmer Biomet 2024 mymobility Commercial Plans Brochure.[53]

Standard features of mymobility include monitoring tools (with customized quarterly report extracts), connectivity features, integration with WalkAI[****], and customer support, with extended data reporting, education customization, and telehealth support available as additional add-ons (Table 6).[53] Various joint-specific and QoL-centric PROMs are available for each procedure, with up to 2 joint and up to 2 QoL PROMs selectable for each procedure (Table 7).[53] Gait exceptions (notifications for PKA/TKA/THA patients whose walking speed is slower than expected) are available for smartphones with iOS 14 and above, and shoulder mobility metrics are available with iPhone 10 or higher (with iOS 14 and above) or Android devices with ARCore™ processors.[51]

[§§§]Hospital for Special Surgery and the HSS logo are trademarks of Hospital for Special Surgery.

[****]WalkAI is available for patients undergoing a hip or knee replacement using the mymobility app on an iPhone 8 or higher supported by the current or previous version of iOS.

Table 5: Standard Features of mymobility

Standard Application Features	

• Applications provided
  ○ Clinician mobile experience
  ○ Clinician web experience
  ○ Patient mobile app
  ○ Patient web experience
• Monitoring tools
  ○ Mobility/functional data[a]
  ○ Gait quality data
  ○ Intelligent gait exceptions (TKA, PKA, THA only)[b]
  ○ Daily walk goal (TKA, PKA, and THA only)
  ○ Patient engagement data (adherence, pain, opioid management)
  ○ Heart rate and heart rate variability
  ○ Shoulder ROM[e]
  ○ Fall detection
  ○ Sleep
• Connectivity features
  ○ Asynchronous messaging
  ○ Persona IQ® connectivity (if Persona IQ user)[f]
• Artificial intelligence with WalkAI™
  ○ Predicted progress
  ○ Patient progress monitoring
  ○ Recovery curves
• Customer support
  ○ Remote training and support
  ○ Implementation support
  ○ Remote tech support
• Education customization (only for PKA, TKA, THA, revision knee/hip, hip fracture, shoulder, and sports protocols), including survey tools[c]
	• Standard data reporting
	  ○ Overall admission volume (by quarter)
	  ○ Admitted patient demographics (by gender, average age, device type, procedure)
	  ○ Activation rate (by total and current, or vs. Network)
	  ○ Logins per patient
	• Advanced data reporting
	  ○ Executive summary of available data
	  ○ Mobility data by procedure
	  ○ Outcomes data by procedure and PROM
	  ○ Past medical history information (as reported by patient)
	  ○ Exceptions for pain, opioid, gait, and WalkAI
	  ○ Comparisons to the mymobility de-identified user database and comparative cohorts (as available)
	  ○ Additional reporting (as available)
	  ○ Raw data export
	• Video visits
	• Telehealth[d]
	• In-app Apple watch ordering by patient

CHIRP = Canary Health Implanted Reporting Processor; CTE = Canturio™ Tibial Extension; PKA = partial knee arthroplasty; PROM = patient-reported outcome measure; QoL = quality of life; THA = total hip arthroplasty; TKA = total knee arthroplasty.

[a] Only 1 joint + 1 QoL PROM per procedure are allowed for Core plans, Plus and Advantage plans provide up to 2 joint + 2 QoL PROMs per procedure

[b] Only available for smartphones with iOS 14 and above

[c] Plus and Advantage commercial plans provide open-ended survey tools and the opportunity to add ≥5 fully customized messages into education content; Core plan allows for limited survey customization

[d] Only available for Plus and Advantage commercial plans

[e] Only available for iPhone 10 or higher users, using iOS 14 or newer, or Android devices with ARCore

[f] Disclaimer: The objective kinematic data generated by the CTE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit. For indications, contraindications, warnings, precautions, potential adverse effects and patient counselling information, see the package insert or contact your local representative; visit https://www.zimmerbiomet.com/en for additional product information. Patients must have Internet access and a text-capable mobile device or a compatible smartphone to use mymobility; not all smartphone app features are available with web-based version. Not all patients are candidates for the use of this product and surgeons should evaluate individually to determine which patients are appropriate for therapy at home. All names used in the mymobility app examples and patient data shown herein is fictitious. No identification with actual patients or health care professionals is intended or

should be inferred. Apple and iPhone are registered trademarks of Apple Inc. The Canary Quantiles™ Recovery Curves software provides HCPs with additional aggregate population data when managing a patient's TKA post-surgical care. HCPs can filter or select options for additional views based on patient demographics (e.g. age), to analyze trends and outcomes. The Canary Quantiles Recovery Curves software allows HCPs to view aggregate patient population data to analyze patient recovery progress and direction of outcome. The Canary Quantiles Recovery Curves software does not control the function or parameters of the Canturio™ Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP®) System and is not intended for active patient monitoring. The information in this reference is provided solely for the purpose of acquainting you with Canary Medical Inc. and its subsidiaries (the "Company", "we", "us" or "our"). This reference does not constitute an offer or solicitation to sell any software or services, all of such services shall be subject to separate Terms of Use and/or subscription documentation. All trademarks are the exclusive property of their respective owners.

Source: Zimmer Biomet 2024 mymobility Commercial Plans Brochure,[53] mymobility website 2023[51]

Table 6: Patient-reported Outcomes Measures Available for mymobility

Procedure Type	PROMs
PKA/TKA/THA	Joint: HOOS, HOOS JR, KOOS, KOOS JR, Oxford Hip/Knee Score[a], Forgotten Joint Score – Knee/Hip[a], LEAS[a] QoL: PROMIS-10, VR-12, EQ-5D-5L[a], NRS pain[a], VAS pain[a], SANE[a]
Revision Hip/Knee	Joint: HOOS, HOOS JR, KOOS, KOOS JR, Oxford Hip/Knee Score[a], Forgotten Joint Score – Knee/Hip[a] QoL: PROMIS-10, VR-12, EQ-5D-5L [a], NRS pain[a], VAS pain[a], SANE[a]
HSS (PKA/TKA/THA)	Joint: HOOS JR, KOOS JR, LEAS QoL: PROMIS-10, NRS pain
Total/Reverse Shoulder Arthroplasty	Joint: DASH[a], Quick DASH, ASES, SST[a], Oxford Shoulder Survey[a], Penn Shoulder Score[a] QoL: VR-12[a], PROMIS-10, EQ-5D-5L, NRS pain[a], VAS pain[a], SANE[a]
Sports (Knee)	Joint: LEFS, IKDC QoL: PROMIS-10, EQ-5D-5L
Sports (Shoulder)	Joint: Quick DASH, ASES QoL: PROMIS-10, EQ-5D-5L
Hip Fracture	Joint: HOOS, HOOS JR, Oxford Hip Score[a], Forgotten Joint Score[a], LEAS[a], LEFS[a] QoL: PROMIS-10, EQ-5D-5L[a], VR-12, NRS pain[a], VAS pain[a], SANE[a]
Rotator Cuff Repair[a]	Joint: DASH, Quick DASH, ASES, SST, Penn Shoulder Score QoL: VR-12, PROMIS-10, EQ-5D-5L, NRS pain, VAS pain, SANE
Shoulder Instability[a]	Joint: DASH, Quick DASH, ASES, SST, Penn Shoulder Score, WOSI QoL: VR-12, PROMIS-10, EQ-5D-5L, NRS pain, VAS pain, SANE
Meniscectomy[a]	Joint: LEFS, IKDC QoL: VR-12, PROMIS-10, EQ-5D-5L, NRS pain, VAS pain, SANE
Meniscal Repair[a]	Joint: LEFS QoL: VR-12, PROMIS-10, EQ-5D-5L, NRS pain, VAS pain, SANE
ACL Reconstruction[a]	Joint: LEFS, IKDC QoL: VR-12, PROMIS-10, EQ-5D-5L, NRS pain, VAS pain, SANE

ACL = anterior cruciate ligament; ASES = American Shoulder and Elbow Score; DASH = Disabilities of the Arm, Shoulder and Hand; EQ-5D-5L = EuroQol–5 Dimensions, 5 Levels; HOOS = Hip Disability and Osteoarthritis Outcome Score; HOOS JR = Hip Disability and Osteoarthritis Outcome Score–Joint Replacement; HSS = Hospital for Special Surgery; IKDC = International Knee Documentation Committee; KOOS = Knee Disability and Osteoarthritis Outcome Score; KOOS JR = Knee Disability and Osteoarthritis Outcome Score–Joint Replacement; LEAS = Lower Extremity Activity Scale; LEFS = Lower Extremity Functional Scale; NA = not applicable; NRS = numerical rating scale; PKA = partial knee arthroplasty; PROMIS-10 = Patient-Reported Outcomes Measurement Information System–10; QoL = quality of life; SANE = single assessment numeric evaluation; SST = Simple Shoulder Test; THA = total hip arthroplasty; TKA = total knee arthroplasty; VAS = visual analog scale; VR-12 = Veterans RAND 12 Item Health Survey; WOSI = Western Ontario Shoulder Instability Index

[a] Only available for Plus and Advantage commercial plans

Source: Zimmer Biomet 2024 mymobility Commercial Plans Brochure.[53]

3 Value Evidence Supporting mymobility

3.1 Summary

Summary Points	Section
• The clinical value of mymobility in joint arthroplasty was assessed in a prospective, multicenter RCT, designed to evaluate whether mymobility-guided education and exercise, paired with remotely captured activity data, offers a clinically effective alternative to the current SoC while reducing overall HCRU. ○ Follow-up is ongoing from a larger correlative cohort, as mymobility facilitates tracking of patient recovery parameters for up to 1 year post-procedure.	Section 3.2
• In the RCT cohort of the clinical trial (N=817), mymobility demonstrated clinical and functional outcomes comparable to traditional care models in both knee and hip arthroplasty. ○ In secondary analyses of the correlative cohort, tracking patient recovery via both functional and physical activity parameters allowed identification of factors that contribute to delayed or inadequate recovery (e.g., chronic pre-operative opioid use, shorter post-operative walking sessions, fewer post-operative step counts)	Section 3.3

• mymobility produced QoL outcomes comparable to traditional care models in both knee and hip arthroplasty cohorts of the RCT.
  ○ Based on secondary analyses of the correlative cohort, mymobility was associated with notable gains in patients with more limited pre-operative mobility and higher baseline comorbidity burden.
  ○ Patients reported high satisfaction (>80%) with the mymobility platform, and the majority of patients cited reduced surgery-related anxiety and increased preparedness for surgery and recovery.
  ○ Use of mymobility also enabled significantly higher patient compliance rates with PROM collection, particularly in older patients (≥65 years), compared to traditional data collection and follow-up.
	Section 3.4

• The use of mymobility was associated with a significant decrease in physiotherapy visits compared to standard follow-up for both TKA/PKA patients and THA patients ($p<0.001$ for both), with no significant change in unplanned office visits, urgent care visits, or readmissions. ○ One-year follow-up data for the PKA/TKA cohort showed a sustained and significant reduction in both physiotherapy visits ($p<0.001$) and ER visits ($p=0.03$) with mymobility vs SoC.	Section 3.5
• A cost comparison analysis based on data from the TKA/PKA cohort of the mymobility clinical study, performed from the perspective of an integrated healthcare delivery system, estimated significantly decreased costs in the mymobility group. ○ The decreased HCRU associated with mymobility translated to a significant mean decrease of $720.02 per patient (or $208,328 for the full group, N=452) over 90 days post-surgery, taking into account the cost of the mymobility system ($p=0.001$).	Section 3.6

Summary Points	Section
• In addition to the results from the mymobility clinical study, evidence supporting the value of RTM in joint arthroplasty is available from several studies of virtual rehabilitation and remote/telemonitoring platforms, which have shown lower HCRU and costs compared to standard follow-up, driven by fewer physiotherapy visits and shorter post-operative LOS. ○ Strong engagement and patient satisfaction were also noted for joint arthroplasty recipients who used RTM, with improved PROM compliance and post-operative log-in frequency versus traditional follow-up across age categories. ○ When surveyed, patients have noted a preference for remote follow-up; citing a reduced burden of travel time/distance and financial costs for both patients and caregivers.	Section 3.7

3.2 The mymobility Clinical Study

The comparative efficacy of mymobility versus standard of care (SoC) for management of patients undergoing total knee arthroplasty (TKA), partial knee arthroplasty (PKA), or total hip arthroplasty (THA), has been investigated in a prospective, multicenter, randomized controlled trial (RCT; NCT03737149).[62] The objective of this study is to determine whether mymobility-guided education and exercise, paired with activity data captured remotely via an Apple Watch, offers a clinically effective alternative to the current SoC while reducing overall HCRU.[63]

All data below, describing the clinical efficacy, safety, and quality of life outcomes with mymobility, are sourced from this study unless otherwise noted.

3.2.1 Study Design

Per the study protocol, enrolled patients underwent a TKA, PKA, or THA procedure with standard protocols and commercially available devices.[63] Patients in the control group subsequently completed the SoC peri-operative and post-operative protocol at their respective institutions; although these protocols were not standardized, nearly all institutions prescribed in-person physiotherapy (most commonly 3 times per week for 4 weeks).[62,65] Patients in the intervention group received an Apple Watch and the mymobility app, which provided pre- and post-operative education and an app-based in-home exercise program (6 to 8 exercises, performed 3 times per day and 6 times per week, for 6 weeks post-surgery).[62,65] Patients in the mymobility group were not prescribed a formal in-person physiotherapy regimen, but could be prescribed in-person physiotherapy to address gait difficulties, ROM limitations, or strengthening needs at the discretion of their surgeon.[65]

This study was designed with three stages:[62,63]

- Cohort 1: a pilot cohort to determine site staffing and time requirements (completed in April 2019)
- Cohort 2: an RCT comparing mymobility to SoC follow-up (completed in February 2020)
- Cohort 3: a correlative analytics cohort enrolling patients from the first and second stages (completed enrollment [N=6,601] in July 2023; data collection ongoing as of April 2024)

RCT cohort: In the RCT stage of the prospective study, the primary endpoint is the readmission rate at 1 month post-surgery, with key secondary endpoints including the following outcomes, assessed at 30 and 90 days post-surgery:[63,64]

- Knee Injury and Osteoarthritis Outcome Score – Joint Replacement (KOOS JR) or Hip Injury and Osteoarthritis Outcome Score – Joint Replacement (HOOS JR) for PKA/TKA and THA procedures, respectively
- EuroQol–5 Dimensions–5 Levels (EQ-5D-5L) scores
- Incidence of manipulation under anesthesia (MUA)
- Timed Up and Go test (time to rise from a chair, walk 10 feet, turn around, walk back to the chair and sit down)
- Single Leg Stance (SLS) test scores (best of 3 tests, up to 60 seconds each)
- Patient satisfaction and engagement, per survey
- HCRU over the entire episode of care (90 days), including physiotherapy visits, discharge disposition, readmissions, reoperations, unscheduled surgeon visits, and ER visits

The assessment schedule includes 3 in-office assessments (approximately 30 days prior to surgery, and 30 days and 3 months after surgery) and 2 virtual assessments (approximately 6 months and 1 year after surgery).[63] Thus, the clinical endpoints described above will be assessed in the RCT cohort through 1 year of follow-up.[64]

Correlative cohort: In addition to the primary analyses described above, performed in the RCT cohort, a variety of secondary analyses will be conducted in the correlative cohort, which includes all mymobility study participants.[64] These analyses will assess both functional outcomes (KOOS JR, EQ-5D, SLS, Timed Up and Go) and physical activity parameters (mean daily steps, flights of stairs, gait speed, and gait asymmetry), and will evaluate the impact of various patient and disease characteristics on recovery of these metrics.[67-71,73-76] The goal of these assessments is to develop correlative measures that will aid surgeons in better understanding and managing risk in their patient populations.[64]

Results from each cohort are summarized in the dossier as follows:

- RCT results are presented by procedure type in the following sections: TKA (Section 3.3.1.1, Section 3.4.1.1, Section 3.5.1), PKA (Section 3.3.2.1, Section 3.4.2.1, Section 3.5.1), THA (Section 3.3.3.1, Section 3.4.3.1, Section 3.5.2)
- Secondary analysis results are presented by procedure type in the following sections: TKA (Section 3.3.1.2, Section 3.4.1.2), PKA (Section 3.3.2.2, Section 3.4.2.2), THA (Section 3.3.3.2, Section 3.4.3.2)

3.2.2 Eligibility Criteria

Eligible patients were ≥18 years of age, qualified for a primary unilateral TKA, PKA, or THA, and mobile (i.e., no more than a single cane or crutch assist pre-operatively).[63,65] Patients were also required to have an iPhone capable of pairing to the Apple Watch and compatible with the mymobility app.[63] Patients were excluded from enrollment if they were 1) members of a protected population (e.g., prisoner or mentally incompetent), 2) currently abusing drugs or alcohol, 3) diagnosed with a systemic inflammatory arthropathy, 4) participating in other surgical interventions or physiotherapy that might compromise study results, or 5) required simultaneous or staged bilateral replacements <90 days apart.[63]

3.2.3 Patient Characteristics

Patient demographics and pre-operative clinical characteristics were generally well-balanced between treatment groups (Table 8), with the exception of age and baseline HOOS JR score in the THA cohort;

patients in the control group were younger by a mean of 3.0 years, and had a 3-point lower mean HOOS JR score (minimal clinically important difference [MCID] of 7 to 16).[62,65]

Table 7: Baseline Patient Characteristics in the mymobility Clinical Study (RCT Phase)

Characteristic	PKA		TKA		THA	
	mymobility (n=48)	SoC (n=59)	mymobility (n=160)	SoC (n=185)	mymobility (n=167)	SoC (n=198)
Age, mean years (SD)	61.6 (9.4)	62.6 (9.3)	63.2 (8.6)	64.5 (8.9)	62.9 (10.4)	59.9 (9.8)
BMI, mean kg/m^2 (SD)	30.4 (5.4)	29.8 (5.9)	32.2 (6.4)	31.3 (6.5)	29.9 (6.2)	29.3 (6.1)
Sex, n Male:Female	18:30	29:30	54:106	75:110	81:86	78:120
Procedure (%) • Anterior • Direct Lateral • Posterior	—	—	—	—	 • 37.1 • 2.4 • 60.6	 • 43.1 • 4.5 • 52.5
KOOS/HOOS JR score, mean (SD)	54.6 (10.9)	53.4 (13.4)	50.5 (13.3)	49.0 (14.5)	52.3 (12)	49.3 (13.1)
EQ-5D, mean (SD)	0.7 (0.2)	0.6 (0.3)	0.6 (0.2)	0.6 (0.2)	0.5 (0.3)	0.5 (0.3)
Passive ROM, mean (SD)	127.1 (7.9)	125.2 (10.8)	116.7 (12.3)	117.4 (11.7)	—	—

BMI = body mass index; EQ-5D = EuroQol–5 Dimensions; HOOS-JR = Hip Disability and Osteoarthritis Outcome Score for Joint Replacement; KOOS-JR = Knee Disability and Osteoarthritis Outcome Score for Joint Replacement; PKA = partial knee arthroplasty; RCT = randomized controlled trial; ROM = range of motion; SD = standard deviation; SoC = standard of care; THA = total hip arthroplasty; TKA = total knee arthroplasty

Source: Crawford et al, 2021 and Crawford et al, 2021.[62,65]

3.3 Clinical and Functional Outcomes

In the RCT phase of the study, the mymobility platform demonstrated clinical and functional outcomes comparable to traditional care models across joint arthroplasty procedures.[62,65,66] In secondary analyses of the correlative cohort, mymobility also enabled clinicians to track individual patient's physical recovery via passive collection of physical activity and gait parameters, and more broadly identify factors correlated with risk of delayed recovery (e.g., chronic pre-operative opioid use, decreased post-operative walking bouts and step counts).[67-74]

Clinical and functional outcomes from the mymobility clinical study are presented by procedure type in the sections below.

3.3.1 Total Knee Arthroplasty

The use of mymobility in TKA recipients was associated with comparable functional outcomes vs standard in-person follow-up, with no significant difference in KOOS JR scores through 1 year post-surgery, and no significant difference in SLS times, Timed Up and Go test scores, and mean passive flexion through 3 months post-surgery.[62,66] Tracking of physical activity parameters with the mymobility app showed significant early improvement from baseline, with recovery continuing over a year of post-TKA follow-up.[67]

3.3.1.1 Comparative Functional Outcomes (RCT Cohort)

For patients who received TKA procedures, there were no significant differences between the mymobility and SoC groups for most functional outcomes at 1 months or 3 months post-procedure, including KOOS JR scores, SLS times, Timed Up and Go test scores, and mean passive flexion (Table 9).[62] KOOS JR scores showed statistically higher improvement from baseline to 3 months for the control group compared to the mymobility group (23.8 vs 18.4; p=0.021), but it should be noted that this difference of 5.4 points is below the MCID threshold typically cited KOOS JR (6 to 14 points).[65,187] At 6 months, KOOS JR scores were significantly higher in the SoC group vs the mymobility group, but no significant difference was observed at 1 year of follow-up.[66]

Table 8: Post-operative Functional Outcomes for Total Knee Arthroplasty Patients (mymobility vs Standard of Care)

Outcome	At 1 month		At 3 months		At 6 months		At 1 year	
	mymobility (n=160)	SoC (n=185)	mymobility (n=160)	SoC (n=185)	mymobility (n=119)	SoC (n=185)	mymobility (n=119)	SoC (n=185)
KOOS JR at timepoint, mean (SD)	62.4 (9.8)	64.4 (10.5)	69.4 (12.8)	72.2 (13.3)	76.1 (13.7)	80.6 (14)	82.9 (14.8)	83.5 (14.9)
p-value	0.106		0.097		0.04		0.78	
KOOS JR change from baseline to timepoint, mean (SD)	11.9 (14.0)	15.2 (14.7)	18.4 (16.3)	23.8 (18.8)	23.3 (16.2)	30 (16.4)	30.1 (18.1)	32.9 (16.8)
p-value	0.066		0.021		0.01		0.32	
SLS in seconds[a] at timepoint, mean (SD)	19.1 (19.4)	17.6 (17.7)	22.9 (21.1)	21.6 (19.9)	NR	NR	NR	NR
p-value	0.518		0.651		NR		NR	
TUG in seconds[b] at timepoint, mean (SD)	11.8 (4.8)	12.9 (6.7)	9.6 (3.6)	10.6 (5.4)	NR	NR	NR	NR
p-value	0.146		0.118		NR		NR	
Passive flexion in degrees at timepoint, mean (SD)	105.2 (16.8)	105.6 (16.4)	121.2 (8.9)	118.8 (11.7)	NR	NR	NR	NR
p-value	0.816		0.083		NR		NR	

CI = confidence interval; KOOS-JR = Knee Disability and Osteoarthritis Outcome Score for Joint Replacement; NR = not reported; SD = standard deviation; SLS = single leg stance; SoC = standard-of-care; TUG = Timed Up and Go Test

[a] Calculated as duration of standing on one leg for up to 60 seconds, as a mean of three attempts each

[b] Measured as time for patient to rise from chair, walk a distance of ten feet, turn, walk back and sit in the chair

Source: Crawford et al, 2021, Alexander et al, 2023.[62,66]

3.3.1.2 Tracking Recovery of Physical Outcomes with mymobility (Correlative Cohort)

mymobility also tracked objective physical activity parameters over 12 months after TKA, allowing physicians to set expectations around recovery parameters and identify potential outliers.[67-69] In a secondary analysis of physical activity parameters, mean steps per day and flights of stairs per day improved significantly from baseline by 1 month (p=0.021) and 6 months (p=0.018) post-TKA, respectively (Table 10), while walking asymmetry recovered to pre-operative values by 3 months (Figure 5).[67] The recovery of gait parameters, including gait speed and flights of stairs per day, continued over a year of follow-up, and were noted to be slower than the observed recovery of KOOS JR and EQ-5D values, which showed significant and clinically meaningful increases as soon as 1 month post-surgery (p<0.001).[67]

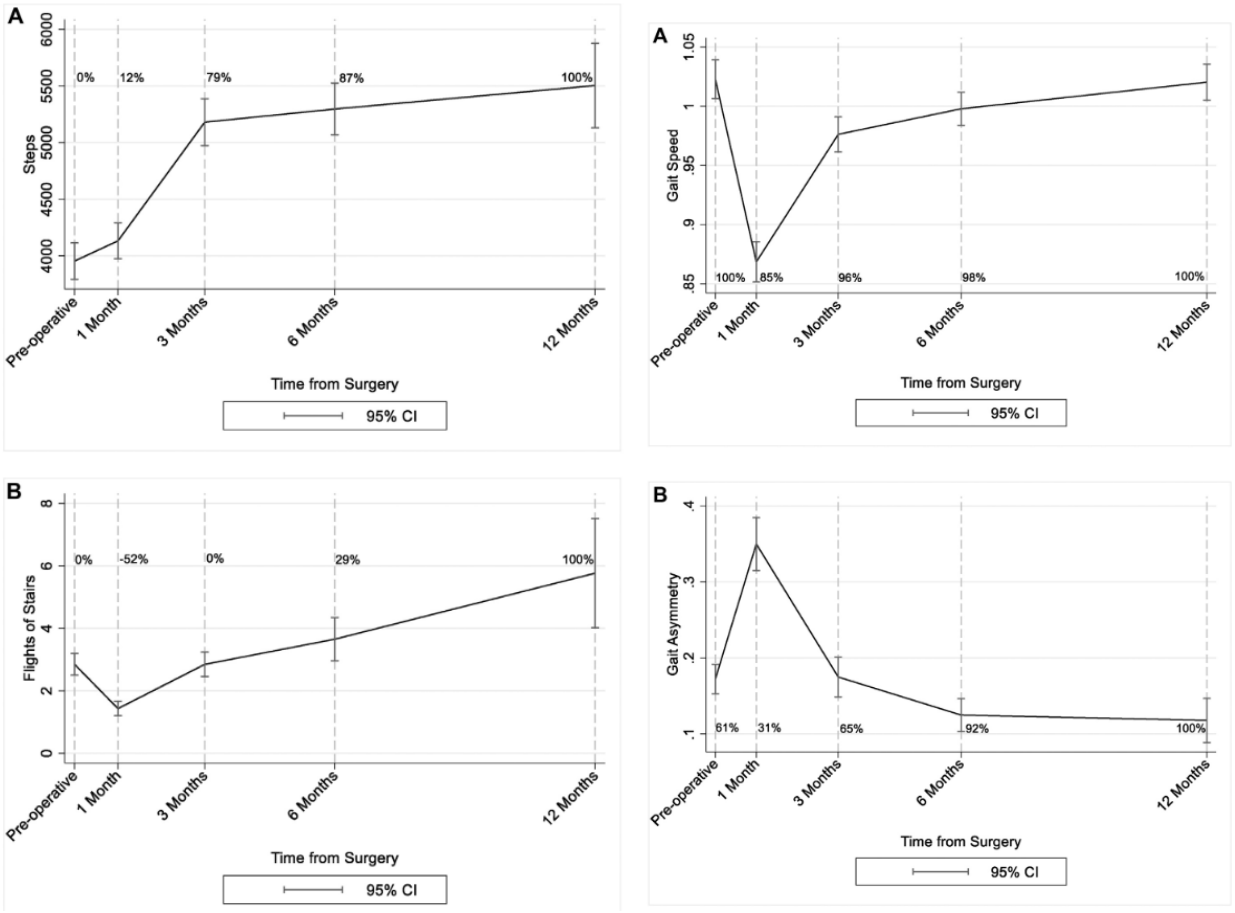
Table 9: Recovery of Physical Activity Measures after Total Knee Arthroplasty for Patients with mymobility

Outcome	Pre-operative (n=1,005)	At 1 month (n=989)	At 3 months (n=938)	At 6 months (n=865)	At 1 year (n=670)
Steps per day, mean (95% CI)	3,953.9 (3,793.9; 4,114.0)	4,132.6 (3,974.3; 4,290.8)	5,180.5 (4,974.2; 5,386.9)	5,296.8 (5,068.1; 5,525.5)	5,504.0 (5,132.6; 5,875.4)
p-value (MCID)	Ref	0.021 (0.14)	<0.001 (0.95)	<0.001 (1.04)	<0.001 (1.20)
Flights of stairs per day, mean (95% CI)	2.84 (2.28; 3.39)	1.40 (0.82; 1.98)	2.83 (2.23; 3.43)	3.65 (3.02; 4.27)	5.62 (4.87; 6.36)
p-value (MCID)	Ref	<0.001 (−0.52)	0.991 (0.00)	0.018 (0.29)	<0.001 (0.99)
Gait speed per day in m/s, mean (95% CI)	1.02 (1.01; 1.04)	0.87 (0.85; 0.88)	0.98 (0.96; 0.99)	1.00 (0.98; 1.01)	1.02 (1.01; 1.04)
p-value (MCID)	Ref	<0.001 (−1.92)	<0.001 (−0.51)	<0.001 (−0.26)	0.191 (0.00)
Gait asymmetry per day, mean (95% CI)	0.18 (0.15; 0.20)	0.36 (0.33; 0.39)	0.17 (0.15; 0.20)	0.12 (0.10; 0.15)	0.11 (0.08; 0.13)
p-value (MCID)	Ref	<0.001 (−1.96)	0.908 (0.11)	0.001 (0.65)	<0.001 (0.76)

CI = confidence interval; MCID = minimal clinically important difference

Source: Christensen et al, 2023.[67]

Figure 5: Gait Recovery Parameters for Total Knee Arthroplasty Patients Tracked Using mymobility



CI = confidence interval

Source: Christensen et al, 2023.[67]

The integrated nature of the mymobility system also enabled detailed analysis of factors that affect patient recovery after TKA, including the impact of baseline and post-operative physical activity and external factors such as access restrictions due to the COVID-19 pandemic.[68,71,75] Early post-operative walking sessions were associated with improved functional outcomes and recovery of gait parameters; e.g., in a cohort of 1,236 TKA recipients who used mymobility, longer walking sessions (defined as walking bouts of ≥20 steps with ≤60 seconds of interruption) at 1 month post-surgery were significantly correlated with faster gait speed (β=0.15; p<0.001) and reduced gait asymmetry (β=−0.03; p<0.001) at 3 months.[68] A similar trend was observed for patients who had more uniform walking patterns (i.e., those who logged qualified walking sessions more evenly throughout the day), where less uniform walking patterns at 1 month were significantly associated with slower gait speed (β=−0.18; p<0.001) and higher gait asymmetry (β=0.03; p<0.01) at 3 months post-surgery.[68] In a smaller cohort of 162 TKA recipients who used mymobility, step counts were also associated with longer SLS times at 1 month and 3 months, and shorter Timed Up and Go test scores at 3 months, suggesting that remotely monitored gait parameters may provide a surrogate measure of functional outcomes.[69]

Patients with lower levels of pre-operative physical activity achieved greater improvements in pain and function following TKA with mymobility; in a secondary post-hoc analysis with a cohort of 1,941 TKA recipients, the high pre-operative physical activity group (75th to 100th percentile of step counts) recovered 88% of their pre-operative steps at 3 months post-TKA, while the medium (25th to 75th percentile) and low (0 to 25th percentile) activity groups exceeded their pre-operative values (104% and 176%, respectively).[75] Patients with low physical activity and medium physical activity also experienced a higher change in KOOS JR scores from baseline to 3 months compared to high physical activity patients (20.2 and 18.7 vs 9.1, respectively; $p<0.05$).[75] Another secondary analysis of patients receiving TKA with mymobility, comparing patients who used opioids ≥90 days prior to surgery (n=72) vs those who did not (n=163) (with propensity score matching for age, body mass index [BMI], sex, Charnley class, ambulatory status, procedure history, and anxiety) found no significant differences in KOOS JR scores through 6 months post-surgery; however, across the broader matched joint arthroplasty population (n=459), patients with chronic opioid use had significantly decreased step counts at 3 months (p=0.02), 6 months (p=0.03), and 12 months (p=0.02), despite no significant difference in pre-operative step counts.[74] Pre-operatively, patients with chronic opioid use were more likely to report moderate to extreme difficulty with moving on the mobility dimension of the EQ-5D, and this difference persisted through 6 months post-surgery.[74]

The effectiveness of self-directed exercise with mymobility was also assessed by comparing cohorts of patients by stage of the COVID-19 pandemic, based on a secondary analysis of 766 TKA recipients.[71] Despite a significant increase in the use of self-directed recovery for TKA patients using mymobility during the earlier stages of the COVID-19 pandemic vs the later stages (35.3% vs. 27.6% respectively; p=0.03), there were no significant differences in recovery of post-operative step counts or the improvement in KOOS JR scores (change from baseline: 17.7 vs 18.4; p=0.54) between the early vs later stage of the pandemic, suggesting that recovery was not limited by the increase in self-directed exercise over in-person physiotherapy.[71]

3.3.2 Partial Knee Arthroplasty

As observed in the TKA population, the use of mymobility produced comparable functional outcomes for PKA recipients vs standard in-person follow-up, with no significant difference in KOOS JR scores through 1 year post-surgery, and no significant difference in SLS times, Timed Up and Go test scores, and mean passive flexion through 3 months post-surgery.[62,66] Based on passive tracking of gait parameters in patients using mymobility, both median gait speed and gait asymmetry recovered to pre-operative values by 3 months post-PKA.[68]

3.3.2.1 Comparative Functional Outcomes (RCT Cohort)

In patients who received PKA procedures (n=107), there were no significant differences between the mymobility and SoC groups for any functional outcomes at 1 months or 3 months post-procedure, including KOOS JR scores, SLS times, Timed Up and Go test scores, and mean passive flexion (Table 11).[62] This trend continued through 1 year of follow-up post-surgery, with no significant differences arising between the mymobility and SoC groups in KOOS JR scores.[66]

Table 10: Post-operative Functional Outcomes for Partial Knee Arthroplasty Patients (mymobility vs Standard of Care)

Outcome	At 1 month		At 3 months		At 6 months		At 1 year	
	mymobility (n=48)	SoC (n=59)	mymobility (n=48)	SoC (n=59)	mymobility (n=41)	SoC (n=56)	mymobility (n=41)	SoC (n=56)
KOOS JR at timepoint, mean (SD)	64.7 (10.7)	68.2 (11.7)	73.3 (11.5)	77.3 (12.9)	80.4 (12.7)	82.1 (13.7)	87.3 (11.2)	84.6 (13.9)
p-value	0.149		0.143		0.64		0.44	
KOOS JR change from baseline to timepoint, mean (SD)	10.1 (13.2)	13.9 (11.4)	18.4 (13.8)	22.8 (15.6)	24.6 (15.0)	26.8 (14.1)	31.5 (14.3)	29.3 (19.7)
p-value	0.167		0.200		0.59		0.64	
SLS in seconds[a] at timepoint, mean (SD)	26.8 (22.1)	19.3 (19.3)	28.5 (19.4)	25.8 (19.4)	NR	NR	NR	NR
p-value	0.101		0.579		NR		NR	
TUG in seconds[b] at timepoint, mean (SD)	10.6 (4.1)	10.4 (3.5)	8.5 (1.9)	8.5 (1.7)	NR	NR	NR	NR
p-value	0.776		0.990		NR		NR	
Passive flexion in degrees at timepoint, mean (SD)	110.0 (15.8)	115.7 (13.3)	123.4 (14.9)	127.5 (9.3)	NR	NR	NR	NR
p-value	0.055		0.147		NR		NR	

KOOS-JR = Knee Disability and Osteoarthritis Outcome Score for Joint Replacement; NR = not reported; SD = standard deviation; SLS = Single leg stance; SoC = standard-of-care; TUG = Timed Up and Go Test

[a] Calculated as duration of standing on one leg for up to 60 seconds, as a mean of three attempts each

[b] Measured as time for patient to rise from chair, walk a distance of ten feet, turn, walk back and sit in the chair

Source: Crawford et al, 2021, Alexander et al, 2023.[62,66]

3.3.2.2 Tracking Recovery of Physical Outcomes with mymobility (Correlative Cohort)

Patient recovery following PKA was tracked by the mymobility app, based on both patient-reported outcomes (e.g., KOOS JR scores) and various gait parameters.[70,71,74] In a cohort of patients who underwent PKA with mymobility (n=233), median gait speed decreased from 0.99 m/s prior to surgery to 0.96 m/s at 30 days post-PKA, and rebounded to 1.01 m/s at 90 days post-PKA; likewise, gait asymmetry returned to pre-operative values by 90 days post-PKA.[68] In another secondary analysis of patients receiving PKA or TKA with mymobility (N=1,121), patients recovered to pre-operative stair counts by 10 to 14 weeks post-procedure, and exceeded pre-operative stair counts by 1 year.[188]

Patients with lower levels of pre-operative physical activity achieved greater improvements in pain and function following PKA with mymobility; in a cohort of 536 PKA recipients, the high pre-operative physical activity group (75th to 100th percentile of step counts), recovered 96% of their pre-operative steps at 3 months post-PKA while the medium (25th to 75th percentile) and low (0 to 25th percentile) activity groups exceeded their pre-operative values.[70] KOOS JR scores remained similar across physical activity levels, but patients with low physical activity experienced a higher change from baseline to 3 months compared to high physical activity patients (21.16 vs 16.52; $p<0.05$).[70] Another secondary analysis of patients receiving TKA with mymobility, comparing patients who used opioids ≥90 days prior to surgery (n=14) vs those who did not (n=22) (with propensity score matching for age, BMI, sex, Charnley class, ambulatory status, procedure history, and anxiety) found no significant differences in KOOS JR scores through 6 months post-surgery.[74] However, as described in Section 3.3.1.2 above, patients with chronic opioid use had significantly decreased step counts at 3 months (p=0.02), 6 months (p=0.03), and 12 months (p=0.02) across the broader matched joint arthroplasty population (n=459), despite no significant difference in pre-operative step counts.[74] Pre-operatively, patients with chronic opioid use were more likely to report moderate to extreme difficulty with moving on the mobility dimension of the EQ-5D, and this difference persisted through 6 months post-surgery.[74]

The recovery of physical outcomes was not significantly impacted by the COVID-19 pandemic for PKA patients using mymobility, based on a cohort of 193 PKA recipients; comparing patients who underwent PKA procedures during the earlier stages of the COVID-19 pandemic (when the incidence of cases were low) to the later stages of the pandemic, there were no significant differences in the use of self-directed therapy (58.9% vs 53.3%; p=0.53), change in post-operative step counts, or change in KOOS JR scores (16.0 vs 16.5; p=0.80).[71] These data further support the hypothesis that patient recovery post-PKA is not limited by the transition from in-person physiotherapy to self-directed rehabilitation.[71]

3.3.3 Total Hip Arthroplasty

As observed with both knee arthroplasty cohorts, the use of mymobility in THA recipients was associated with comparable functional outcomes vs SoC follow-up, with no significant difference in HOOS JR scores through 1 year post-surgery, SLS times and Timed Up and Go test scores at 1 month post-surgery, and hip flexion at 3 months post-surgery.[65] Passive tracking of physical outcomes in patients using mymobility showed that gait parameters typically reached or exceeded baseline levels by 3 months post-THA, and continued to improve through 1 year of follow-up.[72,73]

3.3.3.1 Comparative Functional Outcomes (RCT Cohort)

For patients who received THA procedures, there were no significant differences between the mymobility and SoC groups for most functional outcomes at 1 months or 3 months post-procedure (Table 12).[65] HOOS JR scores showed statistically higher improvement from baseline to 3 months for the control group compared to the mymobility group (33.9 vs 28.4; p=0.011), but it should be noted that this difference of 5.5 points is lower than the typical MCID threshold for HOOS JR (7 to 18 points).[65,187]

Table 11: Post-operative Functional Outcomes for Total Hip Arthroplasty Patients (mymobility vs Standard of Care)

Outcome	At 1 month		At 3 months	
	mymobility (n=167)	SoC (n=198)	mymobility (n=167)	SoC (n=198)
HOOS JR at timepoint, mean (SD)	73.6 (13.0)	73.0 (13.8)	81.4 (12.8)	83.5 (14.5)
p-value	0.660		0.188	
Change in HOOS JR from baseline to timepoint, mean (SD)	20.5 (15.3)	21.9 (17.3)	28.4 (17.0)	33.9 (18.2)
p-value	0.466		0.011	
SLS in seconds[a] at timepoint, mean (SD)	20.7 (19.5)	22.9 (19.8)	22.9 (20.3)	29.9 (20.4)
p-value	0.342		0.013	
TUG in seconds[b] at timepoint, mean (SD)	11.9 (5.0)	11.8 (5.1)	NR	NR
p-value	0.859		NR	
Hip flexion in degrees, mean (SD)	NR	NR	100 (11.3)	101 (10.8)
p-value	NR		0.507	

CI = confidence interval; HOOS-JR = Hip Disability and Osteoarthritis Outcome Score for Joint Replacement; NR = not reported; SD = standard deviation; SLS = single leg stance; SoC = standard-of-care; TUG = Timed Up and Go test

[a] Calculated as duration of standing on one leg for up to 60 seconds, as a mean of three attempts each

[b] Measured as time for patient to rise from chair, walk a distance of ten feet, turn, walk back and sit in the chair

Source: Crawford et al, 2021.[65]

3.3.3.2 Tracking Recovery of Functional and Physical Outcomes with mymobility (Correlative Cohort)

mymobility enabled detailed tracking of HOOS JR and other functional outcomes after THA procedures, including gait and mobility parameters.[72,73] In a cohort of 1,898 patients who underwent THA with mymobility, patient-reported HOOS JR scores were observed to rapidly improve after the THA procedure, with 89.8% of patients achieving the calculated MCID from baseline (defined as a change of ≥6.49 points) by 1 month.[73] HOOS JR scores continued to show improvement at 6 months (85.9; 95% CI: 85.2, 86.7) and 1 year (90.1; 95% CI: 89.1; 91.0), with 98.3% achieving the MCID by 1 year post-surgery.[73]

As observed with the TKA cohort, recovery of gait parameters lagged functional outcomes, but typically reached or exceeded baseline levels by 3 months post-surgery.[73] When assessed for clinical significance, the calculated MCID for step counts was met at 3 months post-surgery (with 66.5% achieving an improvement of ≥1,555 steps) and the MCID for daily flights of stairs was met by 1 year post-surgery (44.5% achieving an improvement of ≥2.9 flights of stairs), but the MCIDs for walking asymmetry (defined as an improvement of 8.9% from baseline) and gait speed (defined as an improvement of 0.07 miles per hour from baseline) were not met through 1 year of follow-up (with only 33.8% and 38.2% achieving the MCID for asymmetry and gait speed recovery at 1 year, respectively) (Table 13).[73]

Table 12: Recovery of Physical Activity Measures after Total Hip Arthroplasty for Patients with mymobility

Outcome[a]	Pre-operative (n=1,898)	At 1 month (n=1,898)	At 3 months (n=1,898)	At 6 months (n=1,898)	At 1 year (n=1,898)
Steps per day	3,931.6 (3,749.0, 4,114.2)	4,848.8 (4,666.2, 5,031.4)	5,750.9 (5,558.2, 5,943.7)	5,890.0 (5,679.9, 6,100.0)	5,665.3 (5,388.4, 5,942.2)
p-value[a]	Ref	<0.001 (56.6%)	<0.001 (66.5%)	<0.001 (68.8%)	<0.001 (68.0%)
Flights of stairs per day	3.07 (2.68, 3.46)	2.43 (2.02, 2.85)	4.45 (4.01, 4.90)	5.12 (4.63, 5.61)	6.15 (5.52, 6.77)
p-value[a]	Ref	<0.001 (19.6%)	<0.001 (33.6%)	<0.001 (38.5%)	<0.001 (44.5%)
Gait speed per day in m/s	1.01 (1.00, 1.01)	0.92 (0.92, 0.93)	1.00 (1.01, 1.04)	1.04 (1.03, 1.05)	1.05 (1.04, 1.07)
p-value[a]	Ref	<0.001 (9.8%)	<0.001 (29.3%)	<0.001 (33.7%)	<0.001 (38.2%)
Gait asymmetry in %	15.5 (13.7, 17.3)	22.8 (20.7, 24.8)	12.2 (10.1, 14.3)	12.0 (9.7, 14.3)	11.3 (7.8, 14.7)
p-value[a]	Ref	<0.001 (17.6%)	0.001 (29.4%)	<0.001 (32.6%)	<0.001 (33.8%)

[a] Reported as mean (95% CI)

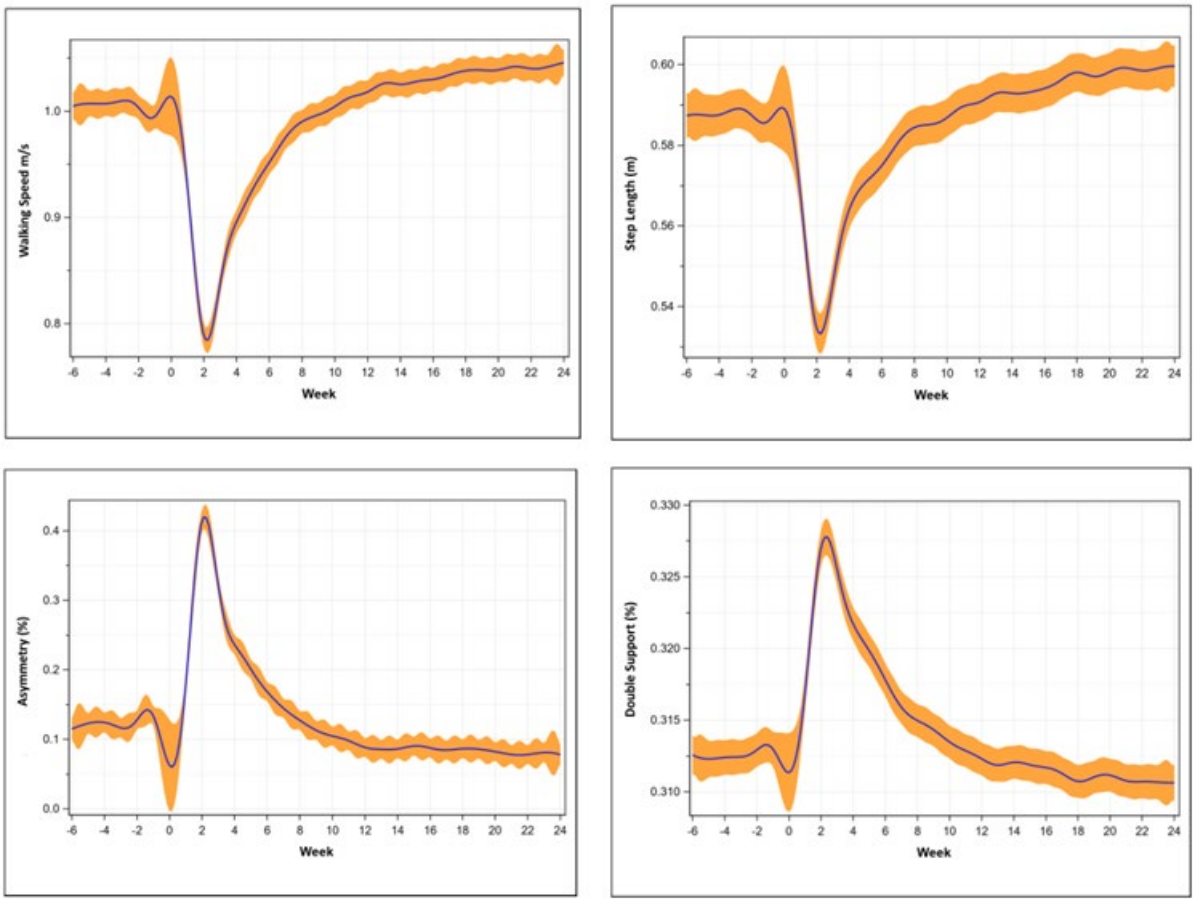
[b] % met MCID

CI = confidence interval; MCID = minimal clinically important difference

Source: Sato et al, 2023.[73]

mymobility also allowed for continuous monitoring of post-THA gait recovery. In a secondary analysis of 612 patients who underwent THA with mymobility, mean walking speed, step length, gait asymmetry, and double limb support were poorest 2 weeks after the procedure ($p<0.001$ for all metrics relative to baseline), but all 4 metrics recovered to values greater than baseline within 10 to 18 weeks (Figure 6).[72]

Figure 6: Continuous Tracking of Gait Recovery Parameters in Total Hip Arthroplasty Patients Using mymobility



CI = confidence interval

Blue lines represent mean values, with 95% CI intervals shown in orange.

Source: Fary et al, 2023.[72]

When mymobility data was used to analyze factors that impact patient recovery after THA, longer and more uniform post-operative walking sessions were associated with faster recovery.[68] In a cohort of patients who underwent THA with mymobility (n=786), improved mobility parameters at 3 months were significantly associated with longer walking sessions (defined as walking bouts with ≥20 steps lasting ≤60 s over flat ground) at 1 month post-surgery, including faster gait speed ($\beta=0.17$; $p<0.001$) and lower gait asymmetry ($\beta=-0.04$; $p<0.001$).[68] A similar trend was also observed for patients who had more uniform walking patterns (i.e., those who logged qualified walking sessions more evenly throughout the day), where less uniform walking patterns at 1 month were significantly associated with slower gait speed

(β=−0.12; p<0.01) at 3 months post-surgery.[68] In a smaller cohort of 174 THA recipients, step counts were also associated with SLS times at 1 month and 3 months (Pearson r=0.40 at 3 months; p=0.0003), and shorter Timed Up and Go test scores at 3 months.[69]

Two secondary analyses assessed the impact of patient baseline characteristics on post-THA recovery. Pre-operative opioid use was evaluated in a cohort of patients receiving THA with mymobility (N=1,198), comparing patients who used opioids ≥90 days prior to surgery vs those who did not (with propensity score matching for age, BMI, sex, Charnley class, ambulatory status, procedure history, and anxiety). Although patients who used opioids ≥90 days prior to surgery had significantly lower baseline HOOS JR scores than patients who did not use opioids (46.2 vs 53.2 respectively, p=0.0004), there were no differences in HOOS JR scores between users and non-users at 3 or 6 months post-surgery.[74] Objective recovery metrics, however, were found to be impacted by chronic opioid use: in the broader matched joint arthroplasty population (n=459), patients with chronic opioid use had significantly decreased step counts at 3 months (p=0.02), 6 months (p=0.03), and 12 months (p=0.02), despite no significant difference in pre-operative step counts.[74] Pre-operatively, patients with chronic opioid use were more likely to report moderate to extreme difficulty with moving on the mobility dimension of the EQ-5D, and this difference persisted through 6 months post-surgery.[74]

The impact of baseline comorbidities was also assessed in an analysis of patients receiving THA with mymobility (N=1,616), which concluded that high baseline comorbidity burden (based on validated measures including depression and anxiety) did not impact baseline HOOS JR scores, but the improvement in HOOS JR scores at 1 year post-procedure was similar for high baseline comorbidity burden patients compared to low baseline comorbidity patients (37.0 vs 33.1 respectively; p=0.01; difference did not reach MCID of 7 to 16).[76]

Finally, the impact of the COVID-19 pandemic on recovery trajectory was evaluated in a secondary analysis of 706 THA recipients.[71] Despite a significant increase in the use of self-directed rehabilitation for THA patients using mymobility during the earlier vs the later stages of the COVID-19 pandemic (72.5% vs 59.3% respectively; p<0.001), there were no significant differences in recovery of post-operative step counts or the improvement in HOOS JR scores (change from baseline: 28.6 vs 29.0; p=0.75) between the early vs later stage of the pandemic, suggesting that recovery was not limited by the increase in self-directed exercise over in-person physical therapy.[71]

3.4 Quality of Life and Patient Outcomes

mymobility has produced QoL outcomes comparable to traditional care models in both knee and hip arthroplasty cohorts of the RCT.[62,65,66] In secondary analyses of the correlative cohort, mymobility was associated with notable gains in patients with more limited pre-operative mobility[70,75] and higher baseline comorbidity burden.[76] Patients reported high satisfaction (>80%) with the platform, with the majority of patients citing reduced surgery-related anxiety and increased preparedness for surgery and recovery.[66] Use of mymobility also enabled significantly higher patient compliance rates with PROM collection, particularly in older patients (≥65 years), compared with traditional data collection and follow-up.[77]

QoL, safety, and patient satisfaction outcomes from the mymobility clinical study are presented by procedure type in the sections below.

3.4.1 Total Knee Arthroplasty

3.4.1.1 Comparative Quality of Life Outcomes (RCT Cohort)

mymobility produced generally comparable QoL outcomes in TKA recipients vs SoC through one year of follow-up, as assessed by EQ-5D scores (Table 14).[62,66] A statistically significant difference between the treatment and control groups was observed at the 6-month timepoint; however, this difference did not exceed the MCID threshold (defined as ≥0.07)[67] and was no longer significant at the 1-year timepoint.[66] Similarly, patient-reported recovery parameters and satisfaction with functional status did not differ significantly between the mymobility vs SoC groups, with the exception of return to sexual activities (a higher proportion of the mymobility group than the SoC group returned to sexual activities at 90 days, however, patients in the SoC group resumed sexual activities sooner on average) (Table 15).[66,189]

Table 13: Post-operative EQ-5D for Total Knee Arthroplasty Patients

EQ-5D	At 1 month		At 3 months		At 6 months		At 1 year	
	mymobility (n=160)	SoC (n=185)	mymobility (n=160)	SoC (n=185)	mymobility (n=119)	SoC (n=185)	mymobility (n=119)	SoC (n=185)
At timepoint, mean (SD)	0.7 (0.2)	0.7 (0.2)	0.8 (0.2)	0.8 (0.2)	0.83 (0.19)	0.88 (0.15)	0.87 (0.17)	0.91 (0.14)
p-value	0.875		0.201		0.04		0.15	
Change from baseline to timepoint, mean (SD)	0.1 (0.2)	0.1 (0.3)	0.2 (0.2)	0.2 (0.3)	0.24 (0.28)	0.26 (0.23)	0.28 (0.27)	0.28 (0.23)
p-value	0.361		0.449		0.61		0.99	

EQ-5D = EuroQol–5 Dimensions; SD = standard deviation; SoC = standard-of-care

Source: Crawford et al, 2021 and Alexander et al, 2023.[62,66]

Table 14: Patient-Reported Recovery and Satisfaction for Total Knee Arthroplasty Patients

Outcome, n (%)	mymobility (n=101)	SoC (n=135)	p-value
Recovery parameters			
Walk without assistive device, n (%)	95 (94.1)	120 (88.9)	0.25
Time since recovery in days, mean (SD)	23.4 (16.7)	30 (22.5)	0.02
Drive independently, n (%)	96 (95.0)	124 (91.9)	0.44
Time since recovery in days, mean (SD)	28.7 (17.0)	32.9 (20.3)	0.14
Return to work, n (%)	45 (44.6)	57 (42.2)	0.79
Time since recovery in days, mean (SD)	37.7 (21.9)	34.2 (23.6)	0.50
Light household activities, n (%)	98 (97.0)	124 (91.9)	0.16
Time since recovery in days, mean (SD)	22.1 (15.6)	26.5 (19.4)	0.11
Heavy household activities, n (%)	52 (51.5)	64 (47.4)	0.60
Time since recovery in days, mean (SD)	49.8 (25.5)	47.2 (19.5)	0.57

Outcome, n (%)	mymobility (n=101)	SoC (n=135)	p-value
Sexual activities, n (%)	59 (58.4)	57 (39.6)[a]	0.01
Time since recovery in days, mean (SD)	42 (19.1)	33.1 (17.4)[a]	0.02
Satisfaction (reported as Likert scale)			
Satisfaction with sitting	79 (78.2)	101 (75.4)	0.64
Satisfaction with lying in bed	72 (71.3)	95 (70.9)	1.00
Satisfaction with getting out of bed	77 (76.2)	99 (74.4)	0.76
Satisfaction with light household duties	79 (78.2)	104 (78.2)	1.00
Satisfaction with leisure recreational activities	65 (64.4)	83 (61.9)	0.79

SoC = standard-of-care

[a] These data included 144 respondents from the SoC group.

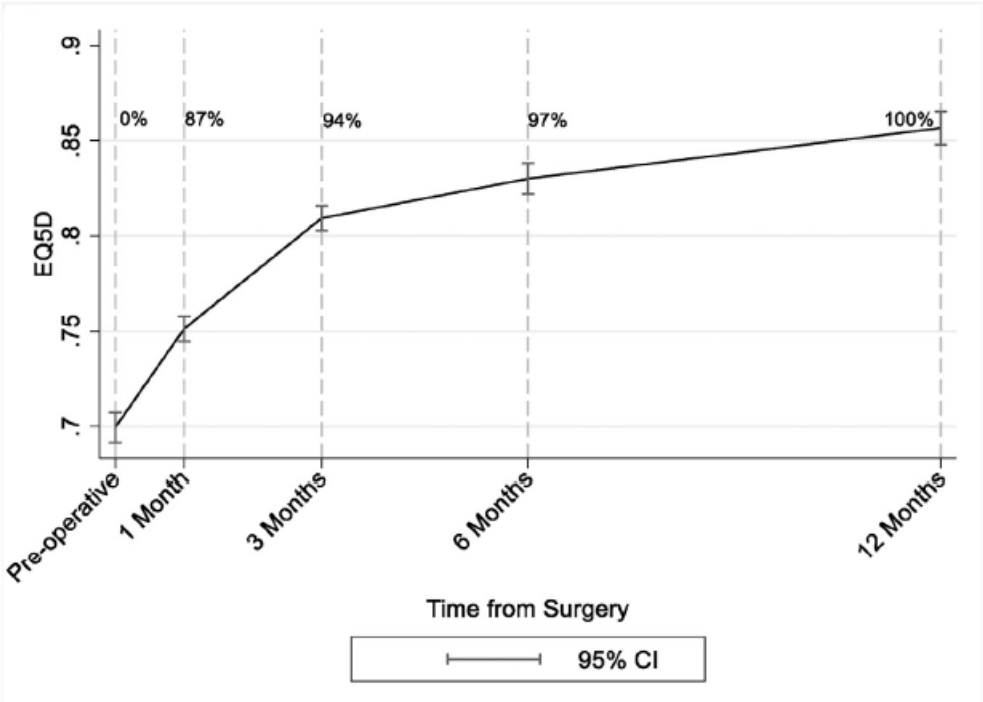
Responses were completed between 59–165 days post-procedure.

Source: Alexander et al, 2023 and DeMik et al, 2023.[66,189]

3.4.1.2 Tracking Quality of Life Recovery with mymobility (Correlative Cohort)

When the recovery of TKA recipients using mymobility was tracked in a secondary analysis (N=1,005), overall EQ-5D scores showed a significant and clinically meaningful increase from baseline as early as 1 month post-surgery (change of 0.05 from baseline; p<0.001 relative to baseline), with 97% of recovery complete by 6-months post-surgery (Figure 7).[67]

Figure 7: Trajectory of EQ-5D Recovery in Total Knee Arthroplasty Recipients



CI = confidence interval; EQ-5D = EuroQol–5 Dimensions

Source: Christensen et al, 2023.[67]

Recovery of EQ-5D scores in the mymobility group was particularly robust in patients with lower pre-operative activity levels. In a secondary analysis of 1,941 TKA recipients using mymobility, comparing patients with high pre-operative physical activity (75th to 100th percentile of step counts), medium physical activity (25th to 75th percentile) and low physical activity (0 to 25th percentile), the high activity group had significantly higher pre-operative EQ-5D index scores compared to the low activity group ($p<0.05$), but the low and medium activity groups had significantly larger improvements in EQ-5D scores at 3 months post-surgery compared to patients with high baseline physical activity ($p<0.05$).[75] Self-rated pain scores via a numeric rating scale (NRS) were similar for all activity level groups at baseline and through 3 months post-surgery, although the reduction in pain from baseline to 3 months post-surgery trended lower for high activity patients (2.54 points) compared to medium activity (2.95 points) and low activity (3.06 points) patients.[75]

Across both TKA and PKA procedures, the only adverse event with significant differences between the mymobility and SoC groups was prolonged wound drainage (n=5 [3.1%] for mymobility vs n=1 [0.4%] for SoC; p=0.04), with no significant differences in the rates of any other adverse events monitored (stiffness, swelling, venous thromboembolism, delayed wound healing, malalignment, superficial site infection, prosthetic joint infection, incision and drainage, reoperation, and revision).[66]

3.4.1.3 Patient Satisfaction

The large majority of TKA recipients surveyed reported a positive impact of the mymobility system on their overall experience (81.6%), citing a better or much better experience compared to previous medical or surgical experiences (78.2%); additionally, the majority of patients noted a positive effect on their preparedness and their surgery-related anxiety (Table 16).[66]

Table 15: Patient-Reported Impact of mymobility on Surgical Experience and Surgery-related Anxiety for Total Knee Arthroplasty Patients

Patient-reported impact	mymobility (n=119)
Significantly positive or positive impact on overall surgical and post-surgical experience, n (%)	80 (81.6)
Significantly positive or positive effect on amount of anxiety, n (%)	57 (58.8)
Significantly more or more prepared for surgery and recovery, n (%)	65 (67.7)
Better or much better experience with mymobility app compared to previous medical and surgical experiences, n (%)	68 (78.2)
Better or much better anxiety with mymobility app compared to previous medical and surgical experiences, n (%)	56 (53.8)

Assessed at 3 months post-surgery with a 5-point Likert scale (from significantly positive impact to significantly negative impact) for each item.

Source: Alexander et al, 2023.[66]

In a combined analysis of the mymobility study and a different study using the FocusMotion†††† mobile app (FocusVentures Inc; Santa Monica, CA) for post-surgical monitoring after PKA or TKA (N=124; 85% TKA), 92.6% of patients found the use of their RTM system easy to use, and 94.5% felt motivated by

†††† FocusMotion is a trademark of FocusVentures, Inc.

their respective app.[79] The majority of respondents agreed with the recommendation of using a combination of inpatient and technology-based rehabilitation (84.4%) and 94.5% would recommend their RTM system to other patients based on their positive experience.[79]

3.4.2 Partial Knee Arthroplasty

3.4.2.1 Comparative Quality of Life Outcomes (RCT Cohort)

mymobility demonstrated comparable QoL outcomes in PKA recipients vs SoC through one year of follow-up, as assessed by EQ-5D scores (Table 17).[62,66] Similarly, patients reported no significant differences in recovery parameters or satisfaction with functional status for mymobility vs SoC within 165 days post-procedure (Table 18).[66]

Table 16: Post-operative EQ-5D for Partial Knee Arthroplasty Patients

EQ-5D	At 1 month		At 3 months		At 6 months		At 1 year	
	mymobility (n=48)	SoC (n=59)	mymobility (n=48)	SoC (n=59)	mymobility (n=41)	SoC (n=56)	mymobility (n=41)	SoC (n=56)
At timepoint, mean (SD)	0.8 (0.2)	0.8 (0.2)	0.8 (0.1)	0.9 (0.1)	0.86 (0.19)	0.91 (0.1)	0.88 (0.18)	0.92 (0.11)
p-value	0.862		0.583		0.18		0.39	
Change from baseline to timepoint, mean (SD)	0.1 (0.2)	0.1 (0.3)	0.2 (0.2)	0.2 (0.3)	0.20 (0.16)	0.28 (0.25)	0.22 (0.22)	0.28 (0.28)
p-value	0.554		0.504		0.17		0.39	

EQ-5D = EuroQol–5 Dimensions; SD = standard deviation; SoC = standard-of-care

Source: Crawford et al, 2021 and Alexander et al, 2023.[62,66]

Table 17: Patient-Reported Recovery and Satisfaction for Partial Knee Arthroplasty Patients

Outcome, n (%)	mymobility (n=39)	SoC (n=46)	p-value
Recovery parameters			
Walk without assistive device, n (%)	37 (94.9)	45 (97.8)	0.59
Time since recovery in days, mean (SD)	22.4 (18.5)	23.6 (25.1)	0.82
Drive independently, n (%)	37 (94.9)	46 (100)	0.21
Time since recovery in days, mean (SD)	26.5 (15)	24.1 (18)	0.54
Return to work, n (%)	15 (38.5)	26 (56.5)	0.13
Time since recovery in days, mean (SD)	34.3 (21.1)	24 (19.5)	0.14
Light household activities, n (%)	37 (94.9)	45 (97.8)	0.59
Time since recovery in days, mean (SD)	23.5 (21.2)	20.5 (18.8)	0.55
Heavy household activities, n (%)	20 (51.3)	30 (65.2)	0.27
Time since recovery in days, mean (SD)	34 (21.6)	39.3 (26.7)	0.49
Sexual activities, n (%)	24 (61.5)	27 (58.7)	0.83
Time since recovery in days, mean (SD)	28.1 (16.8)	34.1 (25.4)	0.39

Outcome, n (%)	mymobility (n=39)	SoC (n=46)	p-value
Satisfaction (reported as Likert scale)			
Satisfaction with sitting, n (%)	33 (84.6)	39 (84.8)	1.00
Satisfaction with lying in bed, n (%)	24 (61.5)	37 (80.4)	0.09
Satisfaction with getting out of bed, n (%)	29 (74.4)	38 (82.6)	0.43
Satisfaction with light household duties, n (%)	30 (76.9)	42 (91.3)	0.08
Satisfaction with leisure recreational activities, n (%)	21 (53.8)	32 (69.6)	0.18

SD = standard deviation; SoC = standard-of-care

Responses were completed between 59–165 days post-procedure.

Source: Alexander et al, 2023.[66]

3.4.2.2 Tracking Quality of Life Recovery with mymobility (Correlative Cohort)

As observed in the TKA cohort, recovery of EQ-5D scores in the mymobility group was greater in patients with lower pre-operative activity levels. In a secondary analysis of 536 PKA recipients, comparing patients with high pre-operative physical activity (75th to 100th percentile of step counts), medium physical activity (25th to 75th percentile) and low physical activity (0 to 25th percentile), the high activity group had significantly higher pre-operative EQ-5D index scores compared to the low activity group (80.4 vs 72.3; $p<0.05$); however, similar changes in EQ-5D scores from baseline were observed for all activity groups through 3 months of follow-up.[70] Self-rated pain scores via NRS were also similar for all activity level groups at baseline and through 3 months post-surgery.[70]

Across both TKA and PKA procedures, the only adverse event with significant differences between the mymobility and SoC groups was prolonged wound drainage (n=5 [3.1%] for mymobility vs n=1 [0.4%] for SoC; p=0.04), with no significant differences observed in any other monitored adverse events (see Section 3.4.1.1).[66]

3.4.2.3 Patient Satisfaction

When PKA recipients were surveyed to assess their satisfaction with mymobility, the majority of patients reported a positive impact of the mymobility system on their overall experience (78.4%), citing a better or much better experience compared to previous medical or surgical experiences (Table 19), and the majority of patients (51.4%) noted a positive effect on their surgery-related anxiety.[66]

Table 18: Patient-Reported Impact of mymobility on Surgical Experience and Surgery-related Anxiety for Partial Knee Arthroplasty Patients

Patient-reported impact, n (%)	mymobility (n=41)
Significantly positive or positive impact on overall surgical and post-surgical experience	29 (78.4)
Significantly positive or positive effect on amount of anxiety	19 (51.4)
Significantly more or more prepared for surgery and recovery	27 (73.0)
Better or much better experience with mymobility app compared to previous medical and surgical experiences	28 (77.8)
Better or much better anxiety with mymobility app compared to previous medical and surgical experiences	24 (63.2)

Assessed at 3 months post-surgery with a 5-point Likert scale (from significantly positive impact to significantly negative impact) for each item.

Source: Alexander et al, 2023.[66]

Patient survey results from an RTM analysis that reported combined results for TKA (n=106) and PKA (n=18) is presented in Section 3.4.1.3.[79]

3.4.3 Total Hip Arthroplasty

3.4.3.1 Comparative Quality of Life (RCT Cohort)

THA recipients reported comparable QoL outcomes with mymobility vs SoC through 3 months of follow-up post-surgery, as assessed by EQ-5D scores (Table 20).[65]

Table 19: Post-operative EQ-5D for Total Hip Arthroplasty Patients

EQ-5D	At 1 month		At 3 months	
	mymobility (n=167)	SoC (n=198)	mymobility (n=167)	SoC (n=198)
At timepoint, mean (SD)	0.7 (0.2)	0.7 (0.2)	0.8 (0.2)	0.8 (0.2)
p-value	0.928		0.549	
Change from baseline to timepoint, mean (SD)	0.3 (0.3)	0.2 (0.3)	0.4 (0.3)	0.3 (0.3)
p-value	0.266		0.393	

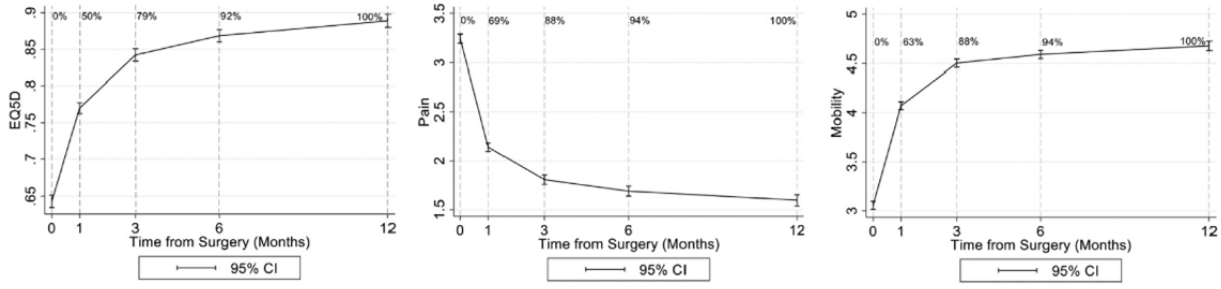
CI = confidence interval; EQ-5D = EuroQol–5 Dimensions; NR = not reported; SD = standard deviation; SoC = standard-of-care

Source: Crawford et al, 2021 and Sato et al, 2023.[65,73]

3.4.3.2 Tracking Quality of Life Recovery with mymobility (Correlative Cohort)

Recovery of QoL post-surgery was tracked in a longitudinal cohort of 1,898 patients who underwent THA with mymobility, in which overall EQ-5D scores were observed to rapidly improve, with 75.3% achieving an MCID of ≥0.07 points by 1 month.[73] EQ-5D scores continued to improve at 6 months (0.87; 95% CI: 0.86, 0.88) and 1 year (0.89; 95% CI: 0.88, 0.89), with 91.1% meeting the MCID by 1 year post-procedure (Figure 8).[73] A similar trend was seen in the EQ-5D Pain and EQ-5D Mobility domain scores, with 97.3% of patients achieving an MCID of −0.37 for the Pain domain and 94.2% achieving an MCID of 0.41 for the Mobility domain by 1 month post-surgery.[73]

Figure 8: Trajectory of EQ-5D Recovery in Total Hip Arthroplasty Recipients



CI = confidence interval; EQ-5D = EuroQol–5 Dimensions

Source: Sato et al, 2023.[73]

Another secondary analysis of THA recipients using mymobility (N=1,616) also found that patients with high baseline comorbidity burden had lower overall EQ-5D scores at baseline than patients with low baseline comorbidity burden (index: 0.408 vs 0.486; p=0.004; VAS: 66.91 vs 72.59; p=0.001); however, the change from baseline in EQ-5D index (0.403 vs 0.391; p=0.69) and EQ-VAS (12.78 vs 14.39; p=0.38) scores were comparable between comorbidity groups through 1 year post-procedure.[76]

3.4.3.3 Patient Satisfaction

In a combined analysis of the mymobility study and a different study using the FocusMotion mobile app for post-surgical monitoring after THA (N=42), 92.7% of patients found the use of their RTM system easy to use, and 87.8% felt motivated by their respective app.[79] The majority of respondents agreed with the recommendation of using a combination of inpatient and technology-based rehabilitation after their THA procedure (90.2%) and 85.4% felt that remote rehabilitation could replace in-person follow-up entirely.[79]

3.4.4 Compliance

Collection of PROM data post-arthroplasty has historically been limited by low compliance rates; however, the majority of mymobility users (n=384) opted to complete their PROMs via the app rather than paper methods (77.5%), enabling higher PROM compliance versus patients followed-up with SoC (n=384), who completed their PROMs through emailed hyperlinks or on paper during clinic visits.[77] Across all procedures, compliance for KOOS JR or HOOS JR was higher for patients with mymobility compared to SoC at baseline (97.1% vs 87.6%; p<0.0001) and through every timepoint up to 1 year post-surgery (71.7% vs 51.6%; p<0.0001).[77] After adjusting for age, sex, procedure, and pre-operative PROM scores, mymobility users were significantly more likely to comply with PROMs at all timepoints (OR: 4.49; 95% CI: 3.30, 6.11; p<0.0001) as well as adhere to Comprehensive Joint Replacement (CJR) guidelines for PROM submission timeframes (OR: 2.08; 95% CI: 1.52, 2.86; p<0.0001).[77] The increased compliance enabled by mymobility was significantly more pronounced for older patients: among patients ≥65 years, 74.1% of patients in the app group remained compliant within CJR timeframes compared to 55.2% of patients in the control group (p<0.0001).[77]

3.5 Economic Outcomes

In the RCT cohort, the use of mymobility was associated with a significant decrease in physiotherapy visits compared to standard follow-up for both PKA/TKA patients (Section 3.5.1) and THA patients (Section 3.5.2) (p<0.001), with no significant change in unplanned office visits, urgent care visits, or readmissions.[62,65] One-year follow-up data is available for the PKA/TKA cohort, showing a sustained and significant reduction in both physiotherapy visits (p<0.001) and ER visits (p=0.03) with mymobility vs SoC.[66]

3.5.1 Total and Partial Knee Arthroplasty

After 3 months following a PKA or TKA procedure, significantly fewer patients using mymobility required in-person physiotherapy visits (59.3%) compared to patients with SoC follow-up (94.4%; p<0.001), and significantly fewer patients required an ER visit (2.5% vs 8.2%; p=0.013).[62] Non-significant reductions in readmissions, non-SoC office visits, and MUA were also observed in the mymobility group vs the SoC group (Table 21).[62]

This significant reduction in physiotherapy visits with mymobility vs SoC was maintained through 1 year of follow-up (60.6% vs 94.6%; p<0.001), as was the significant reduction in ER visits (1.3% vs 5.4% respectively, p=0.03).[66] There were more patients in the mymobility group compared to SoC who required unplanned physician office visits (23.8% vs 19.5% respectively, p=0.32) and hospital readmissions (3.8% vs 2.1% respectively, p=0.36) after 1 year of follow-up, but these differences were not significant.[66]

Table 20: Post-operative HCRU for Knee Arthroplasty Patients (mymobility vs Standard of Care)

Outcome	TKA (3 months)		PKA (3 months)		Combined TKA/PKA (3 months)		Combined TKA/PKA (1 year)	
	mymobility (n=160)	SoC (n=185)	mymobility (n=48)	SoC (n=59)	mymobility (n=208)	SoC (n=244)	mymobility (n=160)	SoC (n=241)
Physiotherapy visits (≥1), %	65.8	93.9	41	96	59.3	94.4	97 (60.6)	194 (94.6)
p-value	<0.001		<0.001		<0.001		<0.001	
Manipulations under anesthesia, n (%)	4 (2.5)	9 (4.9)	0 (0)	0 (0)	4 (1.9)	9 (3.7)	6 (3.8)	12 (5)
p-value	0.274		NA		0.398		0.63	
Unplanned physician office visits (≥1), n (%)	36 (22.5)	43 (23.2)	10 (20.8)	7 (11.9)	46 (22.1)	50 (20.5)	38 (23.8)	47 (19.5)
p-value	0.898		0.288		0.729		0.32	
ER visits, n (%)	5 (3.1)	12 (6.5)	0 (0)	4 (6.8)	5 (2.5)	16 (8.2)	6 (3.8)	13 (5.4)
p-value	0.212		0.126		0.013		0.03	
Urgent care visits, n (%)	2 (1.3)	2 (1.1)	0 (0)	1 (1.7)	2 (1.0)	3 (1.2)	NR	NR
p-value	1.000		1.000		1.000		—	
Readmissions, n (%)	5 (3.1)	10 (5.4)	0 (0)	3 (5.1)	5 (2.5)	13 (6.7)	6 (3.8)	5 (2.1)
p-value	0.429		0.251		0.056		0.36	

ER = emergency room; HCRU = healthcare resource usage; NA = not applicable; NR = not reported; PKA = partial knee arthroplasty; SoC = standard-of-care; TKA = total knee arthroplasty

Source: Crawford et al, 2021 and Alexander et al, 2023.[62,66]

3.5.2 Total Hip Arthroplasty

Significantly fewer THA patients who used mymobility for post-operative follow-up required ≥1 physiotherapy visit at 90 days compared to patients who received standard follow-up (35% vs 57%; p<0.001), with comparable amounts of other types of HCRU (Table 22).[65] Across the entire THA cohort in this study, a greater proportion of individuals who did not need physiotherapy visits (n=84) also achieved a ≥75% compliance for their assigned exercises compared to individuals who did require physiotherapy visits (n=41, 84.5% vs 63.4%).[65]

Table 21: Post-operative HCRU for Total Hip Arthroplasty Patients at 3 Months Post-Surgery

Outcome	mymobility (n=137)	SoC (n=116)
Physiotherapy visits (≥1), %	41 (35.3)	78 (56.9)
No PT visit, n (%)	75 (64.7)	59 (43.1)
p-value	<0.001	
Unplanned physician office visits (≥1), n (%)	62 (39)	57 (37)
p-value	0.812	
ER visits, n (%)	11 (6.6)	10 (5.1)
p-value	0.653	
Urgent care visits, n (%)	2 (1.2)	2 (1.4)
p-value	1.000	
Readmissions, n (%)	7 (4.4)	3 (2.2)
p-value	0.350	

ER = emergency room; HCRU = healthcare resource usage; SoC = standard-of-care

Source: Crawford et al, 2021.[65]

3.6 Econometrics

Considering all patients who received PKA or TKA in the mymobility clinical study, the decreased HCRU associated with mymobility was predicted to translate to significantly lower costs from the perspective of an integrated healthcare delivery system, representing a mean decrease of $720.02 per patient (or $208,328 for the full group, N=452) over 90 days post-surgery, taking into account the cost of the mymobility system (p=0.001; Table 23).[78] Cost savings were primarily driven by a significant decrease in the cost of physiotherapy visits (799 visits for mymobility vs 1,736 visits for SoC; p<0.0001).[78] When considering only the non-crossover group (e.g., patients who did not utilize in-person physiotherapy), the mean cost was reduced by an additional $186 per patient.[78]

Table 22: Estimated Costs Associated with HCRU for Knee Arthroplasty Patients (mymobility vs Standard of Care)

Outcome	mymobility (n=208)	SoC (n=244)	p-value
PT visits[a] total utilization	799	1,736	<0.0001
Total cost per group	$100,674	$218,736	
Mean cost per patient	$680.20	$1,228.90	

Outcome	mymobility (n=208)	SoC (n=244)	p-value
Readmissions, total utilization	5	16	0.055
Total cost per group	$48,615	$155,568	
Mean cost per patient	$233.73	$637.57	
ER visits not resulting in readmissions, total utilization	5	16	0.03
Total cost per group	$2,595	$8,304	
Mean cost per patient	$12.48	$34.03	
Manipulations under anesthesia, total utilization	4	10	0.20
Total cost per group	$6,196	$15,490	
Mean cost per patient	$29.79	$63.48	
Unplanned physician office visits, total utilization	77	67	0.18
Total cost per group	$2,079	$1,809	
Mean cost per patient	$10.00	$7.41	
Urgent care visits, total utilization	2	3	0.79
Total cost per group	$200	$300	
Mean cost per patient	$0.96	$1.23	
mymobility platform, total utilization	208	0	NA
Total cost per group	$28,496	$0	
Mean cost per patient	$137	$0	
Overall cost per group	$188,855	$400,207	0.001
Overall cost per patient	$908.00	$1,640.20	

ER = emergency room; HCRU = healthcare resource usage; NA = not applicable; PKA = partial knee arthroplasty; PT = physiotherapy; SoC = standard-of-care; TKA = total knee arthroplasty

Cost calculations were based on the following input costs: PT visit, $126; Readmission, $9,723; ED visit, $19; MUA, $1,549; office visit, $27; urgent care visit, $27; and mymobility care platform, $137

[a] The number of PT visits was estimated based on categorical collection of data (1–3, 4–6, 7–9, 10–12, or ≥13 visits), with the lowest number of visits in each category used for the total HCRU. Costs of PT visits based on a weighted mean accounting for location (home, outpatient, or both)

Source: Lonner et al, 2023 (submitted manuscript).[78]

Note that no econometric evidence is currently available for THA recipients using mymobility.

3.7 Other Evidence Supporting Remote Therapeutic Monitoring

RTM has been found to reduce HCRU and associated costs in studies across a wide range of platforms and indications, including joint arthroplasty (Section 3.7.1) as well as other respiratory and remote care indications (Section 3.7.2).[30,38,48,190-194] Numerous studies have also linked RTM with improved treatment adherence and high patient satisfaction.[49,195-198]

3.7.1 Non-mymobility RTM Evidence for Joint Arthroplasty

Additional evidence supporting the value of RTM in joint arthroplasty is available from several studies of virtual rehabilitation and remote/telemonitoring platforms, which have shown lower HCRU and costs compared to standard follow-up, driven by fewer physiotherapy visits and shorter post-operative length-of-stay (LOS).[30,38,48]

- The Virtual Exercise Rehabilitation In-home Therapy (VERITAS) trial, a randomized controlled trial (RCT), assessed the effectiveness of the VERA™ platform (Reflexion Health, San Diego CA), a cloud-based telehealth system with 3D tracking technology, digital coaching, and synchronous telehealth with a physical therapist. TKA recipients received either rehabilitation with the VERA platform (n=143) or traditional home and/or clinic-based physiotherapy (n=144). In the VERITAS trial, virtual rehabilitation was associated with a 61% reduction in total costs compared to standard physiotherapy ($1,782 vs $4,527; p<0.001), driven both by significantly fewer physiotherapy visits at 12 weeks (36 vs 686 home health physiotherapy visits and 199 vs 1,450 outpatient physical therapy visits; p<0.001 for both) and reduced rehospitalizations at 12 weeks (12 vs 30; p=0.007).[30]
- Lower costs were also observed in a retrospective analysis of TKA or THA recipients in the Anthem Blue Cross database (N=558, 45% TKA, 2011 to 2016), where patients who received remote guidance and telemonitoring experienced significantly fewer complications (7.0% vs 15.3%; relative risk: 0.456; p=0.004) and incurred significantly reduced 90-day total costs per patient ($651.25 vs $1,307.77 [USD]; p=0.006) compared to patients who received standard outpatient follow-up.[48]
- Telephone-based preparation enabled significant decreases in HCRU compared to patients who received standard surgery preparation in a US prospective study of 476 TKA recipients, including significantly shorter post-operative LOS (mean: 2.0 vs 2.7 days; p<0.001) and significantly fewer discharges with home assistance (42.8% vs 77.2%; p<0.001).[38] Benefits in discharge disposition were also observed for remote surgery preparation compared to standard preparation, including significantly fewer discharges with home assistance (42.8% vs 77.2%; p<0.001), discharges to home with health aide (21.1% vs 31.8%; p=0.04), and discharges to a skilled nursing facility (1.8% vs 21.8%; p<0.0001).[38]

Strong engagement and patient satisfaction were also noted for patients who used RTM in other studies of joint arthroplasty recipients, including a US retrospective study of arthroplasty recipients (N=17,133, 2014 to 2017) which found that patients who used a mobile app for post-operative follow-up had significantly higher PROM compliance and post-operative log-in frequency versus individuals who only used email for submitting questionnaires (p≤0.010 for all age categories).[195] A pilot study that used remote monitoring via a wearable device to collect PROM, kinematic data, and home exercise program compliance for patients undergoing primary TKA (N=25) also found that all respondents at 3 months described the remote monitoring as “engaging” or “motivating”, and the mean daily compliance with home exercise was 62%.[199] TKA and THA patients who received remote follow-up in an RCT (N=55) also reported strong satisfaction, rating their likelihood to recommend remote monitoring as a mean of 8.8 out of 10.[49]

When surveyed, both surgeons and patients have noted a preference for remote follow-up visits. Surgeons who perform joint arthroplasty procedures have supported the use of remote follow-up rather than conventional visits, rating 72% of post-operative visits as appropriate for remote follow-up and only 67% of follow-up visits as “worthwhile” in a national survey (N=195 procedures, 45% TKA).[196]

These survey respondents also generally noted that specific issues and problems warranted in-person visits, while routine follow-up appointments delivered less value and could be done remotely.[196] Conventional follow-up was also noted to burden patients and caregivers; wait times, travel time/distance, and financial costs were the most commonly cited reasons for patient dissatisfaction with conventional follow-up appointments, which were estimated to require a mean of 5.35 person hours per visit (including friends and family who accompanied the patients).[196] 46% of this time was being taken off work, leading to an estimated indirect cost of $68.85 per visit in lost wages.[196]

3.7.2 RTM Evidence in Other Indications

Studies of RTM for patients with chronic obstructive pulmonary disease (COPD), patients who require negative pressure wound treatment (NPWT) and other conditions have found that RTM was associated with improved clinical outcomes, treatment adherence, and patient satisfaction as well as decreased costs and HCRU compared with traditional monitoring (Table 24).[190-194,197,198,200]

Table 23: Benefits of RTM in Other Indications

Reference	Study Design	Patient Population	RTM Intervention	Results
Respiratory indications				
Flynn 2023[190]	Clinical trial	Adult patients with COPD (N=18)	Telehealth- and web-based RTM system	Eight weeks after switching to RTM, patients experienced significant improvements in 6MWT, COPD assessment test, and other scores compared to baseline (p≤0.01 for all)
Benzo 2022[191]	RCT	Adults with COPD (N=375)	Tablet-based patient monitoring system	RTM significantly improved physical and emotional CRQ summary scores vs standard follow-up (p<0.001); all CRQ domains, self-management, daily physical activity, sleep, and depression scores also improved significantly (p≤0.01)
Alshabani 2020[192]	Retrospective analysis	Patients with COPD and high HCRU (N=39)	Electronic inhaler (Propeller)	Significant decrease in COPD-related ER visits or hospitalizations vs SoC (2.2 vs 3.4 respectively; p=0.01) and trend towards lower all-cause ER visits or hospitalizations (3.4 vs 4.7; p=0.06)
Inocencio 2023[a,201]	Budget impact model	Adults with COPD in a commercial or Medicare setting	Electronic inhaler (Propeller)	Use of an RTM inhaler was associated with a decrease of $2,475 per patient per year for commercial payers and $915 per patient per year for Medicare
Sink 2018[202]	RCT	Adults with COPD (N=168)	Telephone-based patient engagement system (Epharmix)	Telemedicine group has significantly improved time-to-hospitalization vs the control group with a HR of 2.36 (95% CI: 1.02, 5.45; p=0.0443); number needed to treat was 8.62
Chen 2019[203]	Prospective single-arm trial	Older adults with COPD (N=190)	Electronic inhaler (Propeller)	Compared to baseline (without RTM), daily and nighttime SABA use significantly decreased and SABA-free days significantly increased up to 12 months (p<0.001 for all)

Reference	Study Design	Patient Population	RTM Intervention	Results
Musculoskeletal and other conditions				
Griffin 2022[193]	Retrospective cohort study	Patients receiving NPWT in the outpatient/post-acute setting (N=1,105)	Telehealth-based RTM service (iOn Progress RTM System)	Total wound-related costs at 90 days were significantly lower for the RTM group compared to the non-RTM group ($11,119 vs $14,752; p=0.0131) after adjusting for age, payer type, CCI score and wound type
Tsvyakh 2021[194]	Prospective clinical study	Polytrauma patients with lower extremity injuries post-surgery (N=48)	Telerehabilitation and home remote monitoring with portable device (with axis, temperature, volume, and pulse sensors)	Patients reported higher satisfaction with telerehabilitation (78.3%; SD: 12.6%) than with traditional orthopedic rehabilitation (36.7%; SD: 7.3%; p=NR), and orthopedic surgeons took significantly less time to consult patients with telerehabilitation (1.9 minutes; SD: 0.5) vs traditional rehabilitation (15.2 minutes; SD: 2.7; p=NR)
Griffin 2019[200]	Retrospective claims analysis (Commercial and Medicare; database NR)	Patients receiving outpatient NPWT (N=431)	Telehealth-based RTM service (iOn Progress RTM System)	Median length of treatment was significantly shorter for RTM compared to non-RTM (27 vs 32; p=0.039) and 90-day wound-related costs trended lower for RTM vs non-RTM ($10,515 vs $12,158; p=NR)
Griffin 2018[197]	Retrospective cohort study	Patients receiving NPWT in a home-care setting (N=510)	Telehealth-based RTM service (iOn Progress RTM System)	Following a reminder call triggered by low adherence (<16 hours/day; actual mean usage 8.7 hours/day), 73.5% of patients increased therapy use by a mean of 7.9 hours/day. Compared to patients with low adherence (<60%), patients with strong adherence (≥90%) had a greater daily reduction rate in wound volume (2.23% vs 1.42%) as well as surface area (1.45% vs 0.86%)
Therapy response				
Godleski 2012[198]	Retrospective cohort study	Patients with diagnoses of schizophrenia, PTSD, depression and/or substance-use disorders (N=76)	Home electronic messaging program	Significant decreases were observed for hospitalizations and ER visits 6 months after the switch to RTM compared to baseline (86% and 66% decrease respectively; p<0.0001 for both). 77% of patients reported they were “Very” or “Fully” satisfied with RTM

6MWT = 6-minute walk test; CCI = Charlson Comorbidity Index; CI = confidence interval; COPD = chronic obstructive pulmonary disease; CRQ = Chronic Respiratory Questionnaire; ER = emergency room; HCRU = healthcare resource usage; HR = hazard ratio; NPWT = negative pressure wound therapy; NR = not reported; PTSD = post-traumatic stress disorder; RCT = randomized controlled trial; RTM = remote therapeutic monitoring; SABA = short-acting beta agonist; SD = standard deviation

[a] Uses outcomes from Alshabani et al, 2020 as clinical input

4 Current Payer Coverage

4.1 Summary

Summary Points	Section
• The RTM family of CPT codes, introduced by CMS as part of the 2022 Physician Fee Schedule, includes 5 codes to parallel the established RPM codes. ○ Includes one code for initial set-up and patient education services (98975), two device codes (98976, respiratory; 98977, musculoskeletal), and two treatment management codes (98980, first 20 minutes; 98981, additional 20 minutes)	Section 4.2
• CMS has not developed a national coverage determination (NCD) for RTM, and no local coverage determinations (LCDs) are available; coverage by commercial payers and state Medicaid programs vary by specific payer.	Section 4.2

4.2 Current Payer Coverage

The RTM family of CPT codes, introduced by CMS as part of the 2022 Physician Fee Schedule, includes one code for initial set-up and patient education services (98975), two device codes (98976, respiratory; 98977, musculoskeletal), and two treatment management codes (98980, first 20 minutes; 98981, additional 20 minutes).[57,178,186] RTM services can be billed once during a 30-day period, provided that ≥16 days of data was collected from the device, a clinician has provided ≥20 minutes of RTM services (e.g., reading and interpreting data/reports, changing care plans, communicating with the patient, documenting the RTM information and services), and the patient or caregiver received ≥1 interactive communication.[57,186] Note that surgeons billing for a global episode cannot bill separately for RTM services during the global pay period. Detailed descriptions and billing requirements for these codes are described in detail in Section 2.4.

As of Q2 2024, CMS has not developed a national coverage determination (NCD) for RTM, and no local coverage determinations (LCDs) are available. Coverage decisions by commercial payers and state Medicaid programs have varied; published medical policies are summarized in Table 25.[204]

Table 24: Commercial and State Medicaid Medical Policies for RTM (as of December 2023)

Payer	Coverage Area	Classification	Policy Statement	Link to Policy
Commercial payers				
BCBS Illinois	IL	Non-covered	RTM codes 98975, 98977, 98980, 98981 are non-covered	https://www.bcbsil.com/docs/provider/il/claims/um/medical-policy-reference-list.pdf
BCBS Kansas City	MO	Non-covered	RTM codes 98975, 98976, 98977, 98978, 98980, 98981 are non-covered	Bluekc.com
BCBS Michigan	MI	Covered • Prior authorization required	RTM is approved when there is an order written by a physician or qualified healthcare practitioner that specifies the medical condition and the length of time for RTM, up to 90 days • BCBSM will not reimburse for the RTM device itself	https://www.bcbsm.com/amslibs/content/dam/public/mpr/mprsearch/pdf/2175944.pdf
BCBS Minnesota	MN	Covered	None	https://www.bluecrossmn.com/sites/default/files/DAM/2023-07/commercial-general-coding-007-telehealth-and-virtual-care-services.pdf
BCBS Mississippi	MS	Covered • Prior authorization required	RTM added to existing RPM policy, but RTM-specific criteria are not included	https://www.bcbsms.com/medical-policy-search#/policy-detail?id=37c94aa7-84ab-4147-8626-5b94c1434803
BCBS North Carolina	NC	Covered	RTM in a non-healthcare setting is considered medically necessary when ALL of the following criteria are met: • RTM is clinically appropriate, in terms of type, quantity, frequency, extent, site and duration and is considered effective for the individual's illness, injury or disease and in accordance with generally accepted standards of medical practice • RTM data is being regularly assessed to detect acute changes in clinical status and prompt intervention • RTM is not primarily for the convenience of the individual, physician, caregiver, or other health care provider • The individual is at risk of clinically significant changes in medical status which warrant enhanced monitoring based on current status and instability of the underlying clinical condition • The individual is unable to access regularly scheduled outpatient clinical care or therapeutic monitoring is required between visits due to potential changes in medical status	https://www.bluecrossnc.com/sites/default/files/document/attachment/services/public/pdfs/medicalpolicy/remote_therapeutic_and_physiologic_monitoring.pdf

Payer	Coverage Area	Classification	Policy Statement	Link to Policy
			• Monitoring is reasonably likely to prevent avoidable deterioration in the clinical condition and/or other adverse events relating to the underlying clinical condition.	
Cigna	National	Non-covered	RTM is considered not medically necessary for all indications.	https://static.cigna.com/assets/chcp/pdf/coveragePolicies/medical/mm_0563_coveragepositioncriteria_remote_patient_monitoring_and_remote_therapeutic_monitoring.pdf
Elevance Health (formerly Anthem)	National	Covered • mymobility classified as non-covered device	RTM in a non-healthcare setting is considered medically necessary when clinical records document the rationale for monitoring including all of the following: • RTM is clinically appropriate, in terms of type, quantity, frequency, extent, site and duration and is considered effective for the individual's illness, injury or disease and in accordance with generally accepted standards of medical practice • RTM data is being regularly assessed to detect acute changes in clinical status and prompt intervention • RTM is not primarily for the convenience of the individual, physician, caregiver, or other health care provider • The individual is at risk of clinically significant changes in medical status which warrant enhanced monitoring based on current status and instability of the underlying clinical condition • The individual is unable to access regularly scheduled outpatient clinical care or therapeutic monitoring is required between visits due to potential changes in medical status • Monitoring is reasonably likely to prevent avoidable deterioration in the clinical condition and/or other adverse events relating to the underlying clinical condition	https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl_pw_e001871.html
Health New England	MA, CT	Non-covered	Additional Non-Covered Procedure Codes and Services • 98975, 98976 and 98977 Remote Therapeutic Monitoring Services • 98980 and 98981 Remote Therapeutic Monitoring Treatment Management Services	https://healthnewengland.org/Portals/_default/Shared%20Documents/providers/EvaluationandManagement.pdf

Payer	Coverage Area	Classification	Policy Statement	Link to Policy
Regence BlueShield	ID, OR, UT, WA	Potentially covered under digital therapeutic products	The use of a digital therapeutic product in the treatment or prevention of any health condition is considered medically necessary when all of the following criteria are met: • The digital therapeutic product has been prescribed by a healthcare practitioner providing medical oversight • The digital therapeutic product has been approved by the FDA for the requested indication • High-quality evidence demonstrates the digital therapeutic product improves clinically meaningful net health outcomes as much or more than an established alternative • The improved net health outcome provided by the digital therapeutic product is attainable outside of investigational settings	https://blue.regence.com/trgmedpol/medicine/med175.pdf
Tricare	National	Non-covered	RTM codes 98975, 98977, 98980 and 98981 are non-covered	https://www.tricare-west.com/content/hnfs/home/tw/prov/auth/symbolic_links/parb.html
Molina	National	Prior authorization required	None	https://www.molinamarketplace.com/-/media/Molina/PublicWebsite/PDF/Providers/oh/medicaid/comm/2022-12-PA-Code-List-PB.pdf
State Medicaid Programs				
Alabama		Non-covered	RTM codes are not included on the Alabama Medicaid fee schedule	https://medicaid.alabama.gov/content/Gated/7.3G_Fee_Schedules.aspx
Alaska		Non-covered	RTM codes are not listed on the Alaska Medicaid Fee Schedule	https://health.alaska.gov/dbh/Pages/Resources/Medicaidrelated.aspx
Arizona		Covered	No published medical policy	—
Arkansas		Non-covered	RTM codes are not included on the Arkansas Medicaid fee schedule	https://humanservices.arkansas.gov/wp-content/uploads/PHYSICN-fees.pdf
California		Non-covered	RTM codes are not included on the Medi-Cal fee schedule	https://mcweb.apps.prd.cammis.medi-cal.ca.gov/rates
Colorado		Covered	No published medical policy	—
Connecticut		Non-covered	RTM codes are not included on the Connecticut Medicaid fee schedule	https://www.ctdssmap.com/CTPortal/Provider/Provider-Fee-Schedule-Download
Delaware		Covered	No published medical policy	—

Payer	Coverage Area	Classification	Policy Statement	Link to Policy
Florida				Non-covered
Georgia		Covered	RTM codes are not included on the Florida Medicaid fee schedule	https://ahca.myflorida.com/medicaid/rules/rule-59g-4.002-provider-reimbursement-schedules-and-billing-codes
Hawaii		Non-covered	No published medical policy	—
Idaho		Non-covered	RTM codes are not included on the Hawaii Medicaid fee schedule	https://medquest.hawaii.gov/en/plans-providers/fee-for-service/fee-schedules.html
Illinois		Covered	RTM codes are not included on the Idaho Medicaid fee schedule	https://publicdocuments.dhw.idaho.gov/WebLink/Browse.aspx?id=3488&dbid=0&repo=PUBLIC-DOCUMENTS&cr=1
Indiana		Covered Prior authorization required	No published medical policy	—
Iowa		• Covered	No published medical policy	—
Kansas		Non-covered	Iowa Medicaid classifies RTM codes (98975, 98977, 98980, 98981) as covered and permanently on the telehealth list	https://hhs.iowa.gov/programs/welcome-iowa-medicaid/policies-rules-and-regulations/covered-services-rates-and-payments/fee-schedules
Kentucky		Covered	RTM codes are not included on the Kansas Medicaid Fee Schedule	https://portal.kmap-state-ks.us/PublicPage/ProviderPricing/FeeSchedules
Louisiana		Non-covered	No published medical policy	—
Maine		Covered	RTM codes are not included on the Louisiana Medicaid Fee Schedule	https://www.lamedicaid.com/provweb1/fee_schedules/feescheduleindex.htm
Maryland		Non-covered	No published medical policy (MaineCare fee schedule only includes 98975 and 98977)	https://mainecare.maine.gov/Provider%20Fee%20Schedules/Forms/Publication.aspx
Massachusetts		Non-covered*	RTM codes are not included on the Maryland Medicaid fee schedule	https://health.maryland.gov/mmcp/pages/provider-information.aspx
Michigan		Non-covered	RTM codes are not included in the current Massachusetts Medicaid fee schedule, but are proposed to be added to the 2024 schedule	https://www.mass.gov/regulations/101-CMR-31700-rates-for-medicine-services
Minnesota		Covered	RTM codes are not included on the Michigan Medicaid fee schedule	https://www.michigan.gov/mdhhs/doing-business/providers/providers/billingreimbursement/physicians-practitioners-medical-clinics
Mississippi		Covered	No published medical policy	—

Payer	Coverage Area	Classification	Policy Statement	Link to Policy
Missouri				Non-covered
Montana		Covered	No published medical policy	—
Nebraska		Non-covered	The RTM codes are listed with a $0 allowable on the Missouri Medicaid fee schedule	https://mydss.mo.gov/mhd/fee-schedules-rate-lists
Nevada		Non-covered	No published medical policy	—
New Hampshire		Covered	RTM codes are not listed on the Nebraska Medicaid fee schedule	https://dhhs.ne.gov/Pages/Medicaid-Provider-Rates-and-Fee-Schedules.aspx
New Jersey		Covered	RTM codes are not listed on the Nevada Medicaid fee schedule	https://dhcfp.nv.gov/Resources/Rates/FeeSchedules/
New Mexico		Covered	No published medical policy	—
New York		Non-covered	No published medical policy	—
North Carolina		Covered	No published medical policy	—
North Dakota		Non-covered	RTM codes are not included on the New York Medicaid fee schedule	https://www.emedny.org/index.aspx
Ohio		Covered	No published medical policy	—
Oklahoma		Non-covered	RTM codes are not included on the North Dakota Medicaid fee schedule	https://www.hhs.nd.gov/healthcare/medicaid/provider/fee-schedules
Oregon		Non-covered	No published medical policy	—
Pennsylvania		Non-covered	RTM codes are not listed on the Oklahoma Medicaid fee schedule	https://oklahoma.gov/ohca/providers/claim-tools/fee-schedule.html
Rhode Island		Covered	RTM codes are not listed on the Oregon Medicaid fee schedule	https://www.oregon.gov/oha/hsd/ohp/pages/fee-schedule.aspx
South Carolina		Non-covered	RTM codes are not listed on the Pennsylvania Medicaid fee schedule	https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/MA-Fee-Schedule.aspx
South Dakota		Non-covered	No published medical policy	—
Tennessee		—	RTM codes are not included on the South Carolina Medicaid fee schedule	https://www.scdhhs.gov/providers/fee-schedules
Texas		Non-covered	RTM codes are not listed on the South Dakota Medicaid fee schedule	https://dss.sd.gov/medicaid/providers/feeschedules/
Utah		Both	Tennessee Medicaid does not publish their own fee schedule	—
Vermont		Non-covered	Texas Medicaid classifies RTM as a non-covered benefit	https://public.tmhp.com/FeeSchedules/Default.aspx
Virginia		Covered Prior authorization required	RTM codes 98980 and 98981 are covered; codes 98975 and 98977 are not covered	https://health.utah.gov/stplan/lookup/CoverageLookup.php

Payer	Coverage Area	Classification	Policy Statement	Link to Policy
Washington		Non-covered	RTM codes are not included on the Vermont Medicaid fee schedule	https://dvha.vermont.gov/providers/codesfee-schedules
Washington DC				Non-covered
West Virginia		• Non-covered	RPM will be covered by FFS and MCOs for post-surgical patients; billing codes covered by this policy include 98975, 98977, 98980, and 98981	https://www.dmas.virginia.gov/for-providers/rates-and-rate-setting/procedure-fee-files-cpt-codes/
Wisconsin				Non-covered
Wyoming		Non-covered	RTM codes are not listed on the Washington Medicaid fee schedule	https://www.hca.wa.gov/billers-providers-partners/prior-authorization-claims-and-billing/provider-billing-guides-and-fee-schedules
			DC Medicaid classifies RTM as a non-covered benefit	https://www.dc-medicaid.com/dcwebportal/nonsecure/feeScheduleInquiry
			West Virginia classifies RTM as a non-covered benefit	https://dhhr.wv.gov/bms/FEES/Pages/default.aspx
			RTM codes are not listed on the Wisconsin Medicaid fee schedule	https://www.forwardhealth.wi.gov/WIPortal/Subsystem/KW/Print.aspx?ia=1&p=1&sa=50&s=5&c=30&nt=Fee+Schedules

BCBS = Blue Cross Blue Shield; FFS = fee-for-service; MCO = managed care organization; RPM = remote physiologic monitoring; RTM = remote therapeutic monitoring

5 Future Directions and Applications

No information for this section.

6 Appendix

6.1 Literature Search Methodology

The search of MEDLINE and Embase electronic databases was conducted, limited to studies published in English (no date limits). The search string ("remote therapeutic monitor*" OR "remote treatment monitor*" OR "RTM").mp was used for both databases. Studies describing the clinical value or unmet need for RTM in joint arthroplasty were selected for inclusion in this dossier; studies supporting the value of RTM in respiratory or other musculoskeletal indications were also collected and summarized as supplemental evidence in Section 3.7.2. Due to a low number of articles identified with conventional searches, a citation-mining approach was also employed, using the bibliographies of the identified papers.

6.1.1 Publication List

Zimmer Biomet-funded publications indicated with an asterisk (*).

6.1.1.1 RTM in Joint Arthroplasty

- Crawford DA, Duwelius PJ, Sneller MA, et al. 2021 Mark Coventry Award: Use of a smartphone-based care platform after primary partial and total knee arthroplasty: a prospective randomized controlled trial. The Bone & Joint Journal. 2021;103-B(6 Supple A):3-12.*
- Crawford DA, Lombardi AV, Berend KR, et al. Early outcomes of primary total hip arthroplasty with use of a smartphone-based care platform: a prospective randomized controlled trial. The Bone & Joint Journal. 2021;103-B(7 Supple B):91-97.*
- Alexander JS, Redfern RE, Duwelius PJ, Berend KR, Lombardi AV, Crawford DA. Use of a Smartphone-Based Care Platform After Primary Partial and Total Knee Arthroplasty: 1-Year Follow-Up of a Prospective Randomized Controlled Trial. J. Arthroplasty. 2023/03/06/ 2023.*
- Redfern RE, Van Andel D, Anderson M, Cholewa J. Does Quality of Life Improve in Patients with Significant Comorbidities Following Total Hip Arthroplasty? Abstract presented at ISTA Annual Conference; September 27-30, 2023; New York City, NY.*
- Christensen JC, Blackburn BE, Anderson LA, et al. Recovery Curve for Patient Reported Outcomes and Objective Physical Activity After Primary Total Knee Arthroplasty: A Multicenter Study Using Wearable Technology. J. Arthroplasty. 2023;38(6):S94-S102.*
- Nelson H, Sheth N, Higuera-Rueda C, et al. Impact of Chronic Opioid Use on Post-Operative Mobility Recovery and Patient Reported Outcomes: A Propensity Matched Study (Submitted Manuscript). 2023.*
- Ribeiro-Castro AL, Surmacz K, Aguilera-Canon MC, et al. Early post-operative walking bouts are associated with improved gait speed and symmetry at 90 days. Gait Posture. 2023/05/20/ 2023.*
- Redfern RE, Anderson M, Van Andel D, Cholewa J. Do Pain and Patient Reported Outcome Measures Vary by Patient Pre-Operative Physical Activity Levels in Partial Knee Arthroplasty Patients? Abstract presented at ISTA Annual Conference; September 27-30, 2023; New York City, NY.*
- Redfern RE, Anderson M, Cholewa J, Van Andel D. Single Leg Stance and Timed Up and Go Tests Are Correlated with Objective Mobility Measures Following Arthroplasty. Abstract presented at ISTA Annual Conference; September 27-30, 2023; New York City, NY.*
- Miner T, Anderson M, Van Andel D, Neher RE, Redfern RE, Duwelius P. Effects of Increased Use of Self-Directed Therapy on Rehabilitation During the COVID-19 Pandemic Following Knee and Hip Arthroplasty. Abstract presented at ISTA Annual Meeting; August 31-September 3, 2022; Maui, HI.*
- Fary C, Cholewa J, Abshagen S, et al. Stepping beyond Counts in Recovery of Total Knee Arthroplasty: A Prospective Study on Passively Collected Gait Metrics. Sensors. 2023;23(12):5588.*
- Sato EH, Stevenson KL, Blackburn BE, et al. Recovery Curves for Patient Reported Outcomes and Physical Function After Total Hip Arthroplasty. J. Arthroplasty. 2023;38(7):S65-S71.*
- Redfern RE, Anderson M, Cholewa J, Van Andel D. Do Pain and Patient Reported Outcome Measures Vary by Patient Pre-Operative Physical Activity Levels in Total Knee Arthroplasty Patients? Abstract presented at ISTA Annual Conference; September 27-30, 2023; New York City, NY.*
- Miller M, Redfern RE, Anderson M, Abshagen S, Van Andel D, Lonner J. Completion of Patient Reported Outcomes Measures Improved with Use of an Arthroplasty-Specific Mobile Application: Results From a Randomized Controlled Trial. Abstract presented at ISTA Annual Conference; September 27-30, 2023; New York City, NY.*

- Booth MW, Riegler V, King JS, Barrack RL, Hannon CP. Patients' Perceptions of Remote Monitoring and App-Based Rehabilitation Programs: A Comparison of Total Hip and Knee Arthroplasty. J. Arthroplasty. 2023;38(7):S39-S43.
- Lonner JH, Naidu-Helm A, Van Andel D, et al. Cost Comparison of a Smartphone-based Care Platform versus Traditional Care in Primary Knee Arthroplasty in the US [submitted abstract]. JMIR mHealth and uHealth. 2023.*
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6.1.1.2 RTM in Other Indications

- Flynn SM, Cornelison S, Pu W, Metzler K, Paladenech C, Ohar J. Feasibility and Efficacy of a Virtual Telehealth Plus Remote Therapeutic Monitoring Pulmonary Rehab Program. Abstract presented at APTA Combined Sections Meeting; February 23-25, 2023; San Diego, CA.
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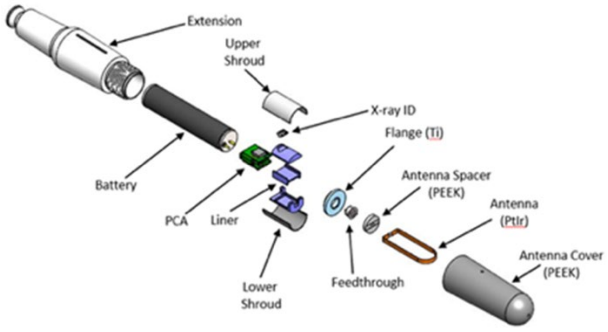
6.2 Persona IQ® The Smart Knee® Implant‡‡‡‡

Persona IQ, the newest component of the ZBEdge suite, is a first-to-world smart knee implant that incorporates the technologies of the Persona Knee system and the CANARY canturio te (CTE) with CHIRP stem extension.[205,206] Persona IQ has received FDA de novo status and Breakthrough Device Designation.[207]

- Persona IQ is indicated for use in patients undergoing a cemented TKA procedure who are normally indicated for at least a 58 mm sized tibial stem extension. Objective kinematic data generated by Persona IQ is not intended to support clinical decision-making.[205,206]
- The Persona IQ stem contains a 3D accelerometer and gyroscope as well as a 10-year lithium carb-monofluoride battery and near-field antenna, which can transmit kinematic data.[208]
    - No Global Positioning System (GPS) capabilities are included in Persona IQ.
- The 3D accelerometer and gyroscope measure kinematic outcomes such as functional ROM (including tibia and functional knee ROM), stride length, qualified step count, and step cadence, as well as estimated distance travelled and average walking speed (based on step count, cadence, and stride length).[205]
    - 3D motion analysis is considered the gold standard for knee kinematics, and 3D inertial gait data can provide information regarding outcomes beyond 2D knee flexion/extension parameters, such as knee alignment and load distribution (which in turn are related to tibial insert wear).[209,210]
- Data from the Persona IQ is wirelessly transmitted to a Home Base station, which in turn automatically sends the data to a HIPAA-compliant Cloud Management platform over Wi-Fi.[211] This automatic data transmission by Persona IQ ensures a consistent cadence of data collection and supports the goal of patient compliance.

‡‡‡‡The kinematic data from Persona IQ have not been demonstrated to have clinical benefit. It is not intended to be utilized for clinical decision-making, and no data have been evaluated by the FDA regarding clinical benefits



- The CTE stem extension is contraindicated for use in patients who are undergoing procedures or treatments at or in the proximity of the CTE using therapeutic ionizing radiation, which can result in shortened battery life or premature failure of electronic components. Damage to the CTE by therapeutic ionizing radiation may not be immediately detectable. The Zimmer Biomet Persona Knee System components are contraindicated for use in patients who have:[205]
    - Previous history of infection in the affected joint and/or other local/systemic infection that may affect the prosthetic joint
    - Insufficient bone stock on femoral or tibial surfaces
    - Skeletal immaturity
    - Neuropathic arthropathy
    - Osteoporosis or any loss of musculature or neuromuscular disease that compromises the affected limb
    - A stable, painless arthrodesis in a satisfactory functional position
    - Severe instability secondary to the absence of collateral ligament integrity

The Persona IQ implant was designed to offer smart post-operative metrics, a connected patient experience and simple to use dashboards and reports. Built-in sensors capture objective kinematic data over the course of patient monitoring and treatment post-surgery, to act as an adjunct to other physiological parameters assessed by the physician.[205,206] Data from Persona IQ also integrates into the ZBEdge platform, providing data for clinicians monitoring patient recovery and treatment post-surgery.[205] This platform provides a direct view of patient-level data for at least 10 years, supporting the goal of patient compliance.[205] Additionally, instrumentation and workflow for Persona IQ remains the same as the standard Persona® The Personalized Knee® implant, Kinematic data can also be viewed along with mymobility data within the OrthoIntel Orthopedic Intelligence Platform.[205]

CMS recently approved a new technology add-on payment (NTAP), designed to cover the additional costs associated with innovative technologies, for Persona IQ. Hospitals performing implantation of Persona IQ on a Medicare beneficiary in the inpatient setting will be eligible for an additional payment of up to $850.85 for a single knee arthroplasty, and up to $1,701.70 for a bilateral knee arthroplasty. This payment is effective October 1, 2023 through September 30, 2024.[212]

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Persona IQ: The objective kinematic data generated by the CTE with CHIRP System are not intended to support clinical decision-making and have not been shown to provide any clinical benefit.

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Patients must have internet access and a text-capable mobile device or compatible smartphone to use mymobility; not all features are available on the web-based version. Patients should be clinically assessed as appropriate candidates for remote care.

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