About this document

This document, prepared by Baker Tilly, LLP at the request of Stryker, presents health plans and providers with clinical and economic information supporting the Mako Robotic-Arm Assisted System (‘Mako’) as a safe and effective surgical tool that surgeons can use to help achieve greater accuracy of component placement and enhance patient satisfaction during hip and knee arthroplasty procedures. Moreover, this document supports Mako’s use within current standard-of-care treatment protocols and reimbursement parameters.

The studies relied on in this document are of varying design, ranging from large randomized controlled trials (RCTs) to single-surgeon studies and cadaver studies. As a result of variations in study design, the robustness of the data arising from different studies may vary. The document includes descriptions of studies relied upon and published sources are cited throughout. We encourage you to consult the cited publications.

Executive reimbursement statement:

Many payers consider the robotic surgical system a tool or technique that is “integral to the primary procedure.” This policy is employed by payers in the U.S. such as UnitedHealthcare and Humana. Moreover, some payers state that “[s]uch matters are left to the discretion of the surgeon.”

Recommended approach, or reimbursement statement, if necessary:

“Robotic-Arm Assisted Systems are integral to the primary surgical procedures (e.g., hip and knee arthroplasties), and as such, these systems are available for surgeons to use at their discretion within existing reimbursement parameters.”

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^ Policies in place as of April 18, 2016.
Purpose:
The purpose of this report is to provide clinical and economic evidence of the Mako Robotic-Arm Assisted System (‘Mako’) to support coverage and adoption of this technology. Mako is an assistive tool that is ancillary to the primary procedure and is designed to enhance the surgical outcome. Mako has demonstrated value to surgeons, patients, hospitals, and payers through clinical and operational benefits. For example, studies have shown surgeons using Mako for assistance in unicompartmental knee arthroplasty (UKA) have demonstrated the following value when compared to non-robotic UKA and/or total knee arthroplasty (TKA) that do not include the Mako Robotic-Arm Assisted System:

- More accurate implant placement\(^1\)\(^-\)\(^3\)
- Lower early post-operative pain\(^4\)
- Reduced average length of stay for the index procedure\(^5\)
- Reduced revision rates at 24 months\(^6\)\(^-\)\(^8\)
A retrospective analysis of the OptumInsight commercial claims database (2013 to 2015) documented the following favorable trends for robotic-assistance associated with UKAs:

<table>
<thead>
<tr>
<th>Category</th>
<th>Non-Robotic UKA</th>
<th>Robotic-UKA</th>
<th>Difference</th>
<th>Percent Reduction</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Index Cases (patients)</td>
<td>1,312</td>
<td>284</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revision Cases (patients)</td>
<td>46</td>
<td>1</td>
<td>-45</td>
<td></td>
<td></td>
</tr>
<tr>
<td>24 Month Revision %</td>
<td>3.5%</td>
<td>0.4%</td>
<td>-3.1%</td>
<td>88%</td>
<td>0.004</td>
</tr>
</tbody>
</table>

In addition, for this same population of commercial patients, all-cause readmissions and their associated payer costs were lower for the robotic-assistance group in key episode-of-care time intervals as follows:

<table>
<thead>
<tr>
<th>Episode Length</th>
<th>30 days</th>
<th>90 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metric</td>
<td>Readmission rate (%)</td>
<td>Allowed per readmission ($)</td>
</tr>
<tr>
<td>Non-robotic</td>
<td>1.10%</td>
<td>15,881</td>
</tr>
<tr>
<td>Robotic assistance</td>
<td>0.70%</td>
<td>15,009</td>
</tr>
<tr>
<td>% Difference</td>
<td>36.36%</td>
<td>872</td>
</tr>
</tbody>
</table>

While these readmission rate and cost findings have substantial quality and patient satisfaction implications, they also suggest that payers, employers, and hospitals participating in bundled payments (i.e., Comprehensive Care for Joint Replacement) may reduce costs for hip and knee arthroplasty surgery when physicians use robotic assistance.

The following is a summary of key value points for Mako which are discussed and sourced in greater detail in the ensuing narrative:

- Since Mako’s market release, over 70,000 joint arthroplasty procedures have been performed using the Mako system. In 2016, Mako is available in less than 5% of U.S. hospitals and is estimated to be utilized for approximately 1% of all applicable joint arthroplasty procedures in the U.S.

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b Analysis conducted by Baker Tilly using a database compiled by OptumInsight, Inc. (Eden Prairie, MN) comprising claims generated by a national commercial health plan consisting of approximately 25 million members. Index cases incurred Jan. 2013 – Dec. 2013, revision cases incurred within 24 months of index procedure. This commercial data has not been blended with Medicare or Medicare Advantage data.


d Analysis conducted by Baker Tilly using Mako volume and installations provided by Stryker Orthopedics.
Over 30 published peer-reviewed studies have reported favorable outcomes with the use of robotic-arm assistance.

A Level 1 randomized controlled trial has demonstrated UKAs with robotic-arm assistance had more accurate implant placement, and less early post-operative pain than non-robotic UKAs.

For total hip arthroplasty (THA), the use of the Mako Total Hip application has demonstrated more accurate component positioning, which may lead to greater range-of-motion, reduced soft-tissue damage, decreased bone-to-bone impingement, and enhanced stability.

Mako can be used in all surgical facility types including ambulatory surgical centers, community hospitals, and large academic centers. This means that payers can potentially benefit from patients seeking care at lower cost, but high quality, ambulatory surgical centers and community hospitals.

Mako facilitates enhanced precision and enables surgeons to perform technically challenging UKA procedures. Several studies have shown that meaningful subsets of patients treated with TKA may have been candidates for UKAs. Moreover, a 2011 study that reviewed surgeries performed by seven (7) clinicians at the same tertiary site found 21% of cases treated with a TKA could have been treated with a UKA.

Note: UKA with robotic-arm assistance has shown a significantly lower adverse event rate (less than 1%) than that of non-robotic UKAs (3.5%) in a retrospective analysis of commercial claims (OptumInsight commercial claims database 2013 to 2015). UKA with robotic-arm assistance also drives lower index and revision procedure costs when compared to non-robotic UKAs and/or TKAs (OptumInsight commercial claims database 2013 to 2015).

To the extent UKA candidates are currently undergoing TKAs, and the use of robotic-arm assistance can allow surgeons to perform UKAs when appropriate in a lower cost outpatient setting, the use of Mako may lead to savings for payers. In an analysis of the OptumInsight commercial claim database (2013 to 2015) with the following conservative assumptions, Mako has the potential to deliver a potential savings of $0.02 to $0.05 Per Member Per Month (PMPM).

- Five to twelve percent (5-12%) of procedures are switched from TKA ($30,982) to robotic-arm assisted UKA ($30,398),
- Ten percent (10%) migration from an inpatient setting to hospital outpatient,
- Reduced readmissions per the study described herein,

Note: If, as seen in the 2011 study referenced above, 21% of UKA candidates were treated with a UKA where robotic-arm assistance was used, the savings can increase to $0.09 PMPM. Furthermore, if a 20% migration from inpatient to hospital outpatient is realized, savings can increase to $0.30 PMPM by 2020.
Introduction:
The Mako Robotic-Arm Assisted System

The Mako Robotic-Arm Assisted System allows surgeons to treat painful knee and hip conditions with reproducible precision and more accurate implant alignment.\(^2,3\) It allows surgeons to optimize current and proven standard surgical approaches for joint arthroplasty. The robotic technology facilitates more accurate component placement\(^1,3,16,19\) and helps to eliminate unnecessary variation in the surgical process across surgeons.\(^4\) The Mako System’s ability to enable surgical and implant placement accuracy begins with patient-specific pre-operative planning. Pre-operative planning is an
essential prerequisite for the success of many orthopedic procedures. Emerging evidence to date suggests that pre-operative planning may be an effective means of favorably influencing the outcomes of orthopedic procedures.\textsuperscript{20} Mako’s pre-operative, computer-assisted 3D planning allows surgeons to evaluate the bone structure, alignment, and joint space as well as the surrounding tissue, so that the surgeon can plan the patient-specific orientation for the implant, select the appropriate size implant, balance the soft-tissue and ensure proper alignment.\textsuperscript{21}

In the operating room, the robotic-arm system provides real-time data to the surgeon, allowing continuous assessment of ligament tension and range-of-motion during implant placement and articulation. Mako technology allows the surgeon to make intra-operative adjustments, as needed, to optimize joint implant placement.\textsuperscript{21} In addition, the real-time data collected through Mako technology enables the surgeon to avoid transection of vital structures, which has shown to reduce blood loss. The decrease in blood loss associated with Mako may be attributed to a number of factors including a smaller incision, decreased soft-tissue trauma, and conservative reaming for hip arthroplasty.\textsuperscript{18} These benefits potentially eliminate the need for routine post-operative hemoglobin monitoring and post-procedure blood transfusions, all factors which could lengthen the patient’s hospitalization.\textsuperscript{22} Importantly, by using real-time data, surgeons are able to refine the surgical plan intra-operatively to achieve soft-tissue balance, resulting in patients who are more likely to forget their artificial joint in daily life.\textsuperscript{23}

The Mako Robotic-Arm Assisted System was released in 2006 for use during partial knee arthroplasty surgery and in 2010 for total hip arthroplasty surgery (Mako plans to have a market release in 2017 for total knee arthroplasty). To date, approximately 70,000 patients or 1% of those receiving a partial knee or hip arthroplasty procedure in the United States have received the benefit of Mako robotic assistance. Over 30 studies summarizing the results of procedures performed with the Mako System, including several randomized trials, have been published in peer-reviewed journals. Results from many of these studies have reported that Mako is associated with enhanced clinical outcomes.\textsuperscript{4,18} Key studies are highlighted in this document. A full bibliography is available upon request.

**Burden of Disease: The Cost of Osteoarthritis is Unsustainable without Treatment Changes**

Osteoarthritis, the most common form of arthritis, affects more people than any other joint disease and is the most widespread cause of walking-related disability in people over the age of 65 years.\textsuperscript{24-26} Osteoarthritis has been estimated to affect nearly 27 million adults in the United States.\textsuperscript{27} Among adults 60 years and older in the United States, an estimated 37.4% have osteoarthritis.\textsuperscript{28} Due to the aging population and increasing trends in joint injury, the number of affected adults with osteoarthritis is expected to increase by about 50% over the next 20 years (with the caveat that past projections have underestimated future burden).\textsuperscript{29}

The morbidity associated with osteoarthritis is considerable:

- 80% of individuals report limitations of movement,
- 25% of those have difficulty performing major activities of daily living.\textsuperscript{30}

While osteoarthritis-related symptoms such as physical pain affect patients’ quality of life, the burden of osteoarthritis extends far beyond that, to encompass the social and personal aspects of everyday functionality.\textsuperscript{31}
The economic burden of osteoarthritis in the United States is estimated to be more than $60 billion per year, with job-related costs reaching as much as $13 billion per year.\textsuperscript{24} As the fourth-most common cause for hospitalization, a diagnosis of osteoarthritis is attributed to approximately 12 million ambulatory care visits and 85,000 emergency room visits per year.\textsuperscript{32}

Osteoarthritis is the leading indication for joint arthroplasty surgery, which is expected to grow exponentially. By 2030, demand for knee arthroplasty is projected to grow by 673\% or to 9.6 procedures per 1,000, while the demand for primary total hip arthroplasty is estimated to grow by 174\% or to 1.6 procedures per 1,000. As the number of primary procedures increases, so will the number of joint revision procedures.\textsuperscript{33} This trend demands that providers and payers collaborate to manage this segment of the population.\textsuperscript{33}

**Joint Arthroplasty - Treatment Complications and Adverse Events**

Joint replacement or arthroplasty is most often performed for painful arthritis that limits activities of daily living and the pain is not relieved by medications or other conservative therapies. Joint arthroplasty has been performed with favorable outcomes over the past several decades and is a proven medical advancement in the field of orthopedic surgery.\textsuperscript{34} That said, a revision procedure may be necessary due to an ineffective primary joint procedure.\textsuperscript{35} This can be due to infection involving the joint, bone loss in the structures supporting the prosthesis, fracture, loosening of the implant, among others.\textsuperscript{36} The risk of an ineffective primary procedure may also be affected by patient factors such as age, weight, activity level, rehabilitation compliance, and the presence of co-morbidities, as well as by the surgical technique. Complications associated with the surgical procedure can include incorrect ligament balancing, poor cement technique, and malrotation of implant parts. Major perioperative adverse events are reported in under 7.5\% of patients and most often become manifest within four days following the implant procedure.\textsuperscript{22,37}

**Clinical Studies**

**Partial Knee Arthroplasty (PKA) with Robotic-Arm Assistance**

For patients who are appropriate candidates for a partial knee arthroplasty (PKA)/unicompartmental knee arthroplasty (UKA), Mako technology can help to preserve healthy ligaments to maintain stability and control. Partial knee arthroplasty for patients with osteoarthritis isolated to only 1 or 2 compartments makes it possible for the surgeon to “save” (i.e., avoid cutting) the anterior cruciate ligament (ACL) and posterior cruciate ligament (PCL), as well as healthy bone and tissue. Minimizing tissue disruption may reduce recovery time, thereby reducing the risk of complications, hospital days, and associated costs.\textsuperscript{38,39} Traditional, non-robotic partial knee procedures, however, are technically challenging and difficult to perform with accuracy, which is why surgeons tend to perform total knee procedures on potential UKA candidates.\textsuperscript{2}

One major limitation of a non-robotic UKA procedure is the high failure rate associated with inaccurate placement of the implant due, in part, to a restricted visual field. Successful UKA requires proper placement of components in multiple planes, where even the slightest abnormality in implant depth can cause complications.\textsuperscript{1} As discussed below, Mako Robotic-Arm assisted procedures may help to overcome the technical challenges associated with non-robotic UKA procedures.
Variability

- Robotic-arm assisted UKA procedures have demonstrated 2 to 3 times less variability when compared to non-robotic procedures, and more reproducible results, allowing for enhanced accuracy with respect to magnitude of tibial slope, degree of error in the coronal plane, and femoral component placement. In a retrospective comparison of patients who underwent Mako Robotic-Arm assisted UKA (n=31 patients) with patients who underwent non-robotic UKA (n=27 procedures) by the same surgeon, tibial component alignment was found to be more accurate and less variable for Mako-guided surgeries compared to those with non-robotic instrumentation.

Implant Placement Accuracy

- In a Level 1 randomized controlled trial (RCT), UKA with robotic-arm assistance showed significantly improved implant placement accuracy compared with non-robotic UKA implantation. In the RCT (n=139 patients) comparing the two techniques for UKA, surgeons using robotic-arm assistance achieved the precise preoperative plan more frequently than when doing non-robotic UKA surgery.

Revisions

- Low revision rates are evidence of enhanced outcomes for robotic-arm assisted UKA patients. In a large multicenter study (n=797 patients; 909 knees) of 6 surgeons, robotic-arm assisted UKA procedures had a cumulative revision rate of 1.2% and high patient satisfaction at an average of 29.6 months follow-up (range: 22 to 52 months). This revision rate is substantially lower than reported rates for non-robotic UKA of 4.5 and 4.8% at a 2-year follow-up (Swedish and Australian national registries, respectively).
Post-Operative Pain and Follow-Up Provider Visits

- Lower post-operative pain and a reduction in office visits and hospitalizations have been experienced by patients. In a prospective, randomized controlled trial (n=139 patients), patients who had UKA with robotic-arm assistance experienced significantly less pain at 7 days (p=0.041) post-operation and greater functioning at 3 months post-operation, as measured by American Knee Society Scores >160 (excellent). Furthermore, the number of office visits to general practitioners and hospitalizations in the 3 months following surgery were also lower for robotic-arm assisted UKA patients.⁴
  - Office visits: 30% (robotic assistance) vs. 45% (non-robotic)
  - Hospitalizations within 3 months of surgery: 3% (robotic assistance) vs. 8% (non-robotic) and;
  - 54 bed-days saved per 100 patients.⁴

Patient Satisfaction

- Patient satisfaction scores are also evidence of enhanced outcomes for patients who underwent a UKA with robotic-arm assistance. At the 2-year follow-up, nearly all (92%) patients indicated that they were either very satisfied or satisfied with their robotic-arm assisted UKA procedure.⁶

- Additionally, patients who undergo UKA are more likely to forget their artificial joint in daily life and consequently may be more satisfied. A study of 139 patients found that at both one and two year follow-up, patients who received a UKA with robotic-arm assistance had a higher Forgotten Joint Score (FJS), than patients who received a TKA. (FJS 1 year 73.9 +/- 22.8 vs. 59.3 +/- 29.5; FJS 2 year 74.3 +/- 24.8 vs. 59.8 +/- 31.5 (p = 0.002)).²³

Total Hip Arthroplasty (THA) with Robotic-Arm Assistance

Despite the substantial improvements in THA, due to an increase in THA procedures, complications and early mechanical failures have increased in occurrence.²⁴ Total hip arthroplasty revisions are often linked to malpositioned acetabular components, which may result in:

- dislocation,
- impingement,
- component wear,
- liner fracture.⁴³

During non-robotic THA surgeons may have difficulty visualizing the relationship of the acetabulum to the pelvis and to the functional axis of the body through its spino-pelvic dynamics.⁴⁴ Additionally, they may not visualize the inner contour of the femur that affects the anteversion of the cementless stem.⁴⁵ As discussed below, Mako Robotic-Arm assisted procedures may help to overcome the technical challenges associated with non-robotic total hip arthroplasty procedures.⁴⁰⁻⁴²,⁴⁵,⁴⁶
Dislocations

- Patients have experienced a reduction in dislocations with robot-assisted THA. In a recent study evaluating patients undergoing posterior-approach total hip arthroplasty, individuals undergoing robotic-arm assisted THA experienced significantly fewer dislocations at 6 months compared to those undergoing non-robotic THA (P<0.001)\(^\text{18}\).

- Based on data prospectively collected on primary THAs, using robotic-arm assistance during THA reduced early dislocation rates compared to conventional THA.\(^\text{18,45}\) In this analysis, data were reviewed for all THAs (n=200) conducted consecutively by one surgeon at a single institution in 2011 and 2012. Results included:
  
  - Lower dislocation rates—likely stemming from enhanced accuracy for both acetabular abduction (AAB) and acetabular anteversion (AAV) in the patient group receiving robotic-arm assisted surgery compared with non-robotic THA (0% vs 3%, p<0.05)\(^\text{18,45}\).
  
  - Reduced blood loss in the patient group receiving robotic-arm assisted surgery compared to non-robotic THA (p-value <0.0001)\(^\text{18,46}\).
  
  - Higher modified Harris Hip scores and UCLA activity level at one year in the patient group receiving robotic-arm assisted surgery compared with non-robotic THA.\(^\text{18,45}\)

Implant Stability

- Preservation of acetabular bone during primary THA is important to implant stability and longevity. Eccentric or excessive acetabular reaming may result in many complications that lead to subsequent THA revisions.\(^\text{46}\) In a matched-pair controlled study, robotic-arm assisted THA allowed for the use of smaller acetabular cups in relation to the patient's femoral head size compared to conventional THA. The use of smaller acetabular cups resulted in greater preservation of bone stock which supports implant stability and has been shown to help prevent dislocation.\(^\text{46}\)

Acetabular Cup Implantation

- Optimal positioning of the acetabular component promotes the long-term success of total hip arthroplasty by reducing the rate of adverse outcomes, such as component wear and dislocation, and ultimately a reduction in admissions and revisions. Robotic-arm assistance has demonstrated a significantly greater percent of acetabular components placed in both Lewinnek's and Callanan's safe zones.\(^\text{11}\) Recent studies have demonstrated that optimal acetabular cup implantation in non-robotic cases is achieved less frequently than originally believed.\(^\text{18,45}\) Orientation of the acetabular cup influences the risk of post-operative complications following THA. Studies suggest that the optimal anteversion ranges from 0 to 30° and acceptable inclination ranges from 30 to 50°.\(^\text{43}\) Cup angles that occur outside these optimal ranges increase the risk of complications such as impingement, increased wear at bearing surfaces, and hip dislocation.\(^\text{48}\) Furthermore, the amount of surgical experience does not appear to affect proper cup orientation.\(^\text{48}\)

- A recent study revealed that the acetabular cup was positioned in an ideal range only 50% of the time during traditionally performed procedures (non-robotic).\(^\text{43}\)
In a study comparing non-robotic and robotic alignment techniques, 50 Mako Robotic-Arm assisted THAs were matched to historical non-robotic THAs conducted between 2008 and 2012. One hundred percent (100%) of the Mako Robotic-Arm assisted THAs were placed within an acceptable range for anteversion and inclination vs. only 80% (40/50) of the manually aligned and implanted THAs. Similarly, 92% of the Mako Robotic-Arm assisted THAs were within another generally accepted range (Callanan) vs. only 62% of non-robotic THAs.

In a multicenter study (n=119 Mako Robotic-Arm assisted THA cases), planned cup placement was compared with cup orientation post-operatively. In 95% of cases, cup placements were recorded to be within 5° of the surgical plan, demonstrating that Mako Robotic-Arm assistance provides surgeons with improved measures to facilitate patient-specific planning.

In a 2015 multicenter study (n=1,980, 228 Mako Robotic-Arm Assisted and 1,752 non-robotic THA procedures), robotic-arm assistance resulted in a significantly greater percent of components placed within a recommended range than conventional, x-ray, and fluoroscopic modalities (p <0.05).

Clinical Efficacy Summary

In summary, the use of Mako in both UKA and THA procedures has demonstrated enhanced clinical outcomes and durability through more accurate component positioning/alignment, bone preservation, and the potential for decreased blood loss. This has led to revision rates lower than previously reported in historic registry data, as well as higher patient satisfaction scores. Moreover, many of the technical challenges and increased adverse events associated with non-robotic UKA and THA have been shown to be reduced with the use of robotic-arm assistance.

The Economics of Mako

Joint disease, affecting 13.9% of adults aged 25 years and older, is associated with an extremely high economic burden. More than 600,000 patients in the U.S. had a primary knee arthroplasty surgery in 2010, or 1.9 per 1,000, and as previously mentioned, by 2030 this demand is projected to increase over 600% to 9.6 procedures per 1,000. The demand for primary total hip arthroplasty is estimated to grow by 174% to 1.6 procedures per 1,000.

Robotic-arm assistance enables surgeons performing UKAs to reduce variability, achieve more accurate placement, and reduce revisions, as previously indicated (3.5% vs 0.4%, p=.004, Source: OptumInsight claims data). It is important to note that a revision joint arthroplasty is much more complicated and more costly than the initial operation. The following are results of an analysis of the Medicare population in the U.S. (CMS IPSAF and OPSAF, 2012 to 2014):

- The average cost of a revision following a non-robotic primary knee replacement was greater than $39,000;
- A revision subsequent to a robotic arm-assisted primary knee arthroplasty surgery was $22,941, 40% less expensive than a revision following a non-robotic knee arthroplasty procedure;
- This represents a significant cost savings (over $16,000 per procedure).
Moreover, in the OptumInsight commercial population, robotic assistance is associated with lower all-cause readmission rates for UKA procedures within 30 days (over 36% lower) and 90 days (over 16% lower). These reduced readmission rates, in addition to the lower average cost per readmission for robotic-arm assisted UKA procedures, translates to:

- 40% lower readmission costs @ 30 days
- 66% lower readmission costs @ 90 days

Managing Costs for Patients Requiring Knee Arthroplasty by Incorporating Mako Robotic-Arm

The PMPM spend for primary joint arthroplasty and associated readmissions (including revisions) is approximately $3.50 to $4.00 PMPM in a typical commercial population, a significant line item that Mako can assist in managing. Importantly, demographic trends project increases in osteoarthritis and joint arthroplasty at levels that will require all stakeholders to consider tools like Mako. Such tools can facilitate increased opportunity to provide patients with the right procedure (specific to their joint disease) at the right time, within an episode of care that utilizes services that potentially reduce UKA revision rates as well as subsequent TKA rates.

In a Medicare population (CMS IPSAF and OPSAF, 2012 to 2014), the cost of revision surgery subsequent to a robotic arm-assisted knee arthroplasty procedure is 40% less expensive than a revision following a non-robotic knee arthroplasty procedure ($22,941 for robotic-arm assisted vs. $39,165 for non-robotic). Additionally, in the Medicare population (CMS IPSAF, 2012 to 2014) the average length of stay was 1.1 days shorter for a revision surgery subsequent to a robotic arm-assisted knee arthroplasty procedure than a revision following a non-robotic knee arthroplasty procedure (2.2 vs. 3.3 days). Note: See Appendix for commercial and Medicare claims analysis methodology.

Robotic-Arm Assistance Can Change the Trajectory of Surgical Joint Interventions°

Robotic-arm assistance may allow surgeons to perform UKAs in some patients who traditionally would have undergone a TKA, thereby resulting in a change in practice patterns and surgical setting with a favorable cost impact (robotic UKAs cost $500 less than TKAs on average in a commercial population). To the extent that approximately 5 to 21% of UKA candidates are undergoing TKAs13,14 in an inpatient setting, robotic-arm assistance can facilitate more accurate alignment with less variation, a reduction in readmissions (notably revisions), as well as a shift to an outpatient setting, leading to potential savings of $0.02 to $0.09 PMPM by 2020 in a typical commercial population (OptumInsight data 2013 to 2015). Furthermore, if a 20% migration from inpatient to hospital outpatient is realized, savings can increase to $0.30 PMPM by 2020.

° Analysis conducted by Baker Tilly using a database compiled by OptumInsight, Inc. (Eden Prairie, MN) comprising claims generated by a national commercial health plan consisting of approximately 25 million members. Index cases incurred Jan. 2013 – Dec. 2013, revision cases incurred within 24 months of index procedure. This commercial data has not been blended with Medicare or Medicare Advantage data.
The economic benefits are noteworthy. A review of commercial 2014 data showed an ALOS of 1.8 days for UKA with robotic-arm assistance versus 2.9 days for TKA. Moreover, as previously stated, from the OptumInsight data analysis, the rate of revision following a UKA with robotic-arm assistance is significantly lower than that of a non-robotic UKA (0.4% vs 3.5%, p=.004) in a large commercial data set. Additionally, a recent study showed using robotic-arm assistance in UKA procedures is cost effective compared with non-robotic UKAs providing additional quality-adjusted life years (QALY) and reduced costs in high volume centers.

**Impact on Innovative Reimbursement Models**

April 1, 2016 commenced the Medicare Comprehensive Care Joint Replacement (CJR) model in the U.S., otherwise known as bundled payments. Under CJR, participation is mandatory for 791 hospitals in 67 geographic areas. These hospitals are accountable for the quality and total Medicare cost of care provided to Medicare fee-for-service beneficiaries for lower extremity joint arthroplasty procedures and recovery within 90 days post hospital discharge. Similarly, commercial payers and employers have been implementing bundled payments with hospitals on hip and knee arthroplasty surgeries. For example, The Connecticut Joint Replacement Institute at St. Francis Hospital has rolled out a bundled payment program with ConnectiCare, the Mayo Clinic implemented a bundled payment for knee arthroplasty surgeries covered by Florida Blue, and Johns Hopkins participates in the Employers Centers for Excellence Network which offers bundled payments to large U.S. employers such as Walmart and Lowe’s.

The quality and cost benefits described in this value summary may improve a hospital’s performance in these bundled payment episodes, by potentially reducing those costs associated with complications and adverse events as well as potentially improving quality composite scores for a participating hospital. This projected improvement in quality and cost may further reduce the episode cost for payers and employers.

**Payer Coverage Considerations**

The majority of payers consider robotic-arm assistance integral to the primary joint arthroplasty surgical procedure and not separately or additionally reimbursed. Surgical procedures completed with robotic-arm assistance should be consistent with existing payer coverage policies and current payer contract rates for the primary surgical procedure. For example, as previously stated, the UnitedHealthcare and Humana reimbursement policies on Robotic-Assisted Surgery do not provide for additional reimbursement. However, the lack of incremental reimbursement should not prohibit surgeons from using their professional discretion in deploying robotic-arm assistance.

**Conclusion**

Robotic-arm assistance is an innovative, cost effective solution for payers. The Mako Robotic-Arm Assisted System enables surgeons to treat knee and hip conditions with greater predictability by allowing for more accurate component placement and reproducibility of both partial knee arthroplasty and total hip arthroplasty. This technology can also have a positive impact on patients by potentially reducing post-operative pain, decreasing adverse events, and enhancing their satisfaction with the joint replacement procedure.
With all factors pointing to an increase in the prevalence of joint arthroplasties, it is important to identify technologies to help mitigate rising costs and reduce the overall economic burden of osteoarthritis. Allowing surgeons access to this important safe and effective operating room technology gives surgeons a valuable tool to potentially enhance outcomes, mitigate adverse events, and enhance the patient experience.
APPENDIX:

A summary of the commercial data sources and methods for the commercial claims analyses used in this value summary.

Data Sources

The source for the Commercial data was derived from OptumInsight, Inc. comprising claims generated by a national commercial health plan consisting of approximately 25 million members. The date range of data used is 2013-2015.

Methods

Baker Tilly’s methodology used a retrospective review designed to provide a comparison of medical claims between knee procedures with and without a robotic-arm assistance device. Identification of the knee procedures was determined using the following procedural index events as listed in the Current Procedural Terminology (CPT) and International Classification of Diseases Version 9 (ICD-9) coding manuals. In order to differentiate between UKAs and TKAs, CPT’s were tracked from the professional place of service through to their respective inpatient procedure for the commercial population.

- Unicompartmental Knee Arthroplasty (UKA) is defined by CPT code 27446 and Total Knee Arthroplasty (TKA) is defined by CPT code 27447.
- Robotic cases were determined using the ICD-9 procedure code of 17.41.
- Inpatient revisions were determined using ICD-9 procedure codes 81.54, 81.55 or 00.80-00.84.

Patient Age / Sex Distribution

<table>
<thead>
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<th>Age Band</th>
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</tr>
<tr>
<td>80-99</td>
<td>49%</td>
<td>51%</td>
</tr>
<tr>
<td>Overall</td>
<td>46%</td>
<td>54%</td>
</tr>
</tbody>
</table>
A summary of the Medicare data sources and methods for the Medicare claims analyses used in this value summary.

Data Sources
The Medicare data was derived from the Medicare Inpatient Standard Analytical File (IPSAF) and the Medicare Outpatient Standard Analytical File (OPSAF) for calendar years 2012-2014.

Methods
Baker Tilly’s methodology used a retrospective review designed to provide a comparison of medical claims between knee procedures with and without a robotic-arm assistance device. Identification of the knee procedures was determined using the following procedural index events as listed in the Current Procedural Terminology (CPT) and International Classification of Diseases Version 9 (ICD-9) coding manuals.

- ICD-9 procedure code 81.54 with either DRG 461, 462, 469 or 470 was used to determine knee procedures.
- Robotic cases were determined using the ICD-9 procedure code of 17.41.
- Inpatient revisions were determined using ICD-9 procedure codes 81.54, 81.55 or 00.80-00.84.
- Outpatient revisions were determined using CPT codes 27486 or 27487.
References


Novitas LCD for total hip and knee arthroplasty citing the American Academy of Orthopaedic Surgeons (AAOS) and the American Association of Hip and Knee Surgeons (AAHKS). Model Coverage Determination: Total Joint Arthroplasty.


45Illgen R. Robotic assisted THA: reduce outliers and predictable outcomes. 43rd Annual Course: Advances in Arthroplasty; October 22-25, 2013; Cambridge, MA. (Illgen 2013b)


