IMPLANT WARS

By Jason C. Davis

Despite a reported downturn in inflation, US Healthcare continues to produce shocking examples of out-of-control costs. This reality is clearly seen in the treatment of musculoskeletal diseases. All told, the total direct costs are estimated at over $500 billion per year and rising.[1] According to the American Journal of Orthopedics, over a third of Americans reported some musculoskeletal condition that significantly impaired their normal routines. For many these issues develop into the "need" for serious orthopedic procedures and joint replacements, which are among the most profitable surgeries in all of medicine, typically paying the most money to providers, in ratio to the time a surgeon spends in the operating room.[2]

It therefore comes as no surprise to discover that, in the last 10 years, the occurrence and associated costs of serious orthopedic procedures have jumped by 300%. Current projections are that this trend will continue and we may see a 400% increase in joint replacements by 2030, meaning more implant charges.[3] As it relates to joint replacements, one of the most important cost drivers are implants that can make up 40% to 70% of total procedure costs, rising to 90% for many spine procedures.[4] Moreover, it seems that the questionable quality of the implants, though not entirely responsible for runaway expenses, also adds to the long-term total costs and the theory that many downstream surgeries we will see are going to be "do-overs" (also known as revisions). Why? Because...

> *About 18 percent of hip replacements and about 8 percent of knee replacements in the U.S. are for revision surgery resulting from defective or failed devices. The six best-selling hip and knee implant companies collectively issued 1,334 recalls for components of their devices over the past 10 years.*[5]

This is arguably due in part to the manner in which the implants are approved and cleared for distribution in the US. Currently, implant manufacturers do not need to show that their implants are safe or effective; they simply have to show that it is roughly the same or similar to one that is already approved for use, resulting in over 90 percent of devices being cleared for use without appropriate safety verification.[6]

The bottom line is that the frequency of serious orthopedic procedures and corresponding implant costs, in many markets, have been and continue to be out of control. As such, even the most diligent administrator feels powerless in the face of these excessive costs, finding it nearly impossible to understand or justify network discounts, negotiate claims with providers, get cost information, or apply reasonable and appropriate pricing. In light of this ongoing and concerning trend, it is critical that self-funded payers and their administrators understand this industry, take a hard look at their exposure on high-cost implantable devices, and adopt cost-containment best practices to ensure they are protected from these soaring costs.

More Surgeries

What is the reason for this steady and significant increase in serious orthopedic surgeries and joint replacement procedures? Regardless of whose opinion you read, you will be told that the reason for more orthopedic procedures is because (1) we are getting older, and (2) we are getting heavier. This, however, does not fully capture the often overlooked third factor: consumers are simply being offered greater access to more surgical options. Adjusted data from the Orthopedic and Arthritis Center for Outcomes Research demonstrates that obesity and the aging population fails to account for the 134% increase in total knee replacements between 1998 and 2007 (overall, a 300% increase).[7] So how *do* we account for it?

Though perhaps too simplistic a correlation, the number of ambulatory surgical centers ("ASC") have also doubled in the last 10 years, and more surgeons are securing ownership or a form of financial interest in these ASCs.[8] In fact, there are venture capital firms that seem to specialize in recruiting surgeons to be part-owners of an ASC. "So what," you might ask? Well, one study found that of 941 surgeons that became owners of an ASC, they performed between 52% and 111% more surgeries than non-owners.[9] As one Doctor reminds us, "*Surgeons are busy, and they like to operate. A professor from my residency would say, 'There is nothing more dangerous than a surgeon with an open operating room and a mortgage to pay.'*"[10]

It has been widely documented that the US healthcare system rewards over-utilization, and many hospitals will give bonuses to surgeons if they perform more procedures; it's an "eat what you kill" mentality. One doctor was exposed for performing 500 unnecessary stent procedures with a personal record of 30 in one day![11] The Institute of Medicine has estimated that 30% of all healthcare spending is waste, which includes unnecessary procedures. An example of this is when Medicare discovered that 10% of spinal procedures were performed and paid for, but did not follow established standards of care.[12]

Self-funded payers and their administrators would be well-served to educate consumers on the shortcomings of some surgeries which are often unnecessary, and encourage second opinion protocols. Fortunately, some high-quality facilities have adopted "patient centric" and "collaborative decision making" best practices, and are seeing radical changes in surgical decisions. For example, some have seen up to 50% of spinal fusion referrals end up not being actual candidates for surgery or having greater health benefits through non-invasive treatments.[13]

In light of the above, it is not a stretch to suggest that at least part of the increase in serious orthopedic procedures and joint replacements is attributable to the provider community pushing for these surgical options more often than ever before.

More Costs

Not only has the frequency of serious orthopedic procedures and joint replacement surgeries increased, but so has the cost of the surgical implants involved. For example, hip implant list prices have increased over 300% from 1998 to 2011. A hip implant currently costs approximately $350 to manufacture, but once all the middlemen are paid and the bells and whistles are added, hospitals and physicians end-up paying approximately $4,500 to $7,500.[14]

The final and most significant blow is the mark-up applied by the provider, who now effectively becomes an implant reseller. At The Phia Group, not only are we are seeing a 300% average mark-up on already high-priced implants, but we have also seen other even more egregious charges, such as a hip implant billed at $60,000 (a 1000% mark-up).[15]

A Tale of Two Facilities: Hospitals and ASCs

Hospital CEOs are not compensated on the quality of care they deliver, but rather based on profit, patient volume and marketing campaigns.[16] As a consequence, and subject to a cost assessment and severity-weighted outcome analysis, many larger hospitals often offer lower quality care at much higher prices. How can this be?

Large hospitals have comprehensive services for a variety of conditions ranging from cardiac care, cancer treatments and orthopedics, just to name a few. These large facilities have sizeable fixed costs (65-85%) regardless of how many patients are admitted for care or if their beds remain empty.[17] This "fixed-cost dilemma" means that they are compelled to accept Medicare or Medicaid patients who do not reportedly cover costs. The following is a statement from the American Hospital Association ("AHA") on the topic:

> *Hospital participation in Medicare and Medicaid is voluntary. However, as a condition for receiving federal tax exemption for providing health care to the community, not for profit hospitals are required to care for Medicare and Medicaid beneficiaries. Also, Medicare and Medicaid account for 58 percent of all care provided by hospitals. Consequently, very few hospitals can elect not to participate in Medicare and Medicaid.*[18]

As it relates to implants specifically, the Medicare and Medicaid reimbursement for implants is "bundled" into the total payment of the ambulatory payment classification ("APC") or the diagnostic related group ("DRG"). Since these implants are not separately reimbursable for costs; this often creates a short-fall.

According to the AHA in the "Underpayment by Medicare and Medicaid Fact Sheet 2015" Medicare only pays a hospital on average 88% of their costs whereas Medicaid was found to pay 90%.[19] These payments are particularly challenging for providers regarding implant claims since the implants make up a large portion of the costs that are barely (if at all) being recovered. In the end this means that the bulk of Medicare and Medicaid reimbursements for these services flow directly into the implant manufacturers' and their intermediaries' pockets.

This in turn leads to large hospitals needing to aggressively negotiate with suppliers, possibly limiting implant choices for their surgeons, and shifting costs to private commercial payers in the form of higher charges. This dynamic potentially reduces the quality of the selected implants and may compromise the quality of care.[20]

This does not translate, however, to less patient volume for orthopedic procedures (as one would think), because these large hospitals (typically part of large health systems) also have more healthcare services to offer which means large managed care contracts with major payers, carriers, and PPOs. Further, consumers often associate "bigger" and "more expensive" with "better." For this reason, large hospitals and their associated surgical centers often have the largest market share as it relates to orthopedic surgeries.

In contrast, independent ambulatory surgical centers (ASCs) are smaller facilities that offer only certain types of care like orthopedics. Often these facilities market themselves as "focused factories" which theoretically have the potential to increase value and quality. It is worth noting that these facilities also do not typically accept Medicare or Medicaid patients, and so they do not have to shift costs to private payers as larger hospitals do. This allows for more pricing flexibility.

Dr. Keith Smith of the Oklahoma Surgery Center, an ASC that is pioneering transparent and fair pricing in healthcare, shared the following thoughts on implant charges:

> *We do not mark up the price of implants at our facility. After all, these items are rarely if ever actually part of our inventory, but here on "consignment." Typically an implant representative brings the implants to our facility and an invoice is generated only after we actually use them.* ***I believe that there is no justification for adding a markup to implants that are not part of a facility's inventory, and this is the case for the vast majority of facilities and their relationships with vendors.*** *Fortunately, this "what can I get away with," "who cares what it costs, anyway," method of doing business in the healthcare industry is experiencing the great scrutiny and calumny it deserves.*[21]

If taken at face value, it seems like most providers in fact do not buy or own the implants, nor keep them as part of their inventory. Yet, as we know, most facilities still add a sizeable mark-up on implant charges.

Interestingly, at The Phia Group, we have also seen entities that make this *implicit* consignment business arrangement *explicit* by intermediating the sales and collections of implants. That is, you may get a bill from a hospital for a hip surgery, and a totally separate bill from the implant supplier along with a "supplier cost invoice." Do not confuse this for being the manufacturers invoice as this is likely yet another marked-up claim under the guise of a "direct to supplier" deal. Buyers beware! Without proper cost information, how would you know the difference?

Hospital vs. Independent ASC

Most hospital joint replacements are paid for under some form of a fixed rate contract. As we have said, this is also how Medicare and Medicaid pay for these procedures. In increasing measure, some ASCs are trying to carve out implant reimbursement separately in order to compete with the bigger hospitals. In fact, some ASCs are simply happy to recover their costs if they can secure higher volume contracts with larger payers:

> *We are having success obtaining implant carve outs with our private payers because they recognize the cost savings ASCs offer them.* ***Even securing cost only for implants increases our volume by allowing us to retain cases that would otherwise be sent to the hospital.***[22]

Dr. Keith Smith addresses fair implant pricing as a major competitive edge:

> *Very simply, our refusal to mark up the price of implants has made us very difficult to compete with when it comes to securing the business for individuals and entities with the sticker shock of an actual healthcare consumer.*

Physician-owned independent ASCs can, however, also sometimes have a downside. As mentioned above, this dynamic can lead to over-utilization. We have also seen In-Network (INN) surgeons who actively refer patients to out-of-network (OON) facilities where they are part-owners, and the charges are outrageous. Of course, the Plan can ensure that it has higher cost-sharing for OON providers, but some of these ASCs charge so exorbitantly for the implants that in most cases it does not actually contain costs to have higher member responsibility.

In the end, why would a patient ever "choose" an OON facility and face all the additional "shared" costs that come with it? The Phia Group is seeing that in many instances, there are no actual additional "shared" costs for the member. It seems that there is often a "wink wink / nudge nudge" agreement between the physician and member that he or she will not be billed the balance for going to the OON ASC – and practically speaking, INN or OON is then irrelevant from the patient's perspective.

Large hospital systems have taken notice of the emergence and physician referral advantages of ASCs. Very recently, Tenet Healthcare Corporation announced that they will buy United Surgical Partners International, a major player in promoting physician owned ASCs. As more services migrate to an outpatient setting, and physician owned facilities continue to take a market share (by controlling referrals); look for this trend towards consolidation to continue.

A New Direction: Bundled Payments

Case rates are all-in-one flat rates for facility charges, but a flat rate does not always necessarily mean a fair rate. Some of these "case rates" simply do not produce value for the payer even though the "discount" percentage may appear impressive. For this reason, and for the sake of more price transparency, payers are often favoring contracts with providers for a surgical hosting fee and a "carve-out" for the implants on a "cost-plus" basis. This model is also used by many states for workers' compensation programs.

Recently and in increasing measure, however, the market is producing bundled case rates for orthopedic procedures. A "true" bundled payment (not just an APC or DRG) would typically include defined components of physician care, implant diagnostics, surgery, hospital care, and postoperative care after surgery (typically between 30 and 90 days); all for one fixed price. If there is a post-operative issue related to the surgery, the provider must address it on their dime. Beyond the targeted cost savings, early results show that bundling will improve the quality and value of the care delivered. This makes sense, as the provider offering the bundled services now has control over the entire episode, which should reduce costly readmissions and reduce the unnecessary use of expensive "clinical pathways." Simply stated, the bundling model encourages the right care at the right time; anything more or less is penalized.

Protect the Plan

Now that we have outlined the implant problem and some of the market dynamics, we must look towards best practices. First and foremost, it is important to ensure that your plan document is properly written to ensure that you are protected from high-dollar implant charges. These implant specific definitions and provisions should harmonize with your general usual and reasonable or maximum allowable reimbursement language.

Further, you can consider having the plan not accept a claim as clean or complete until the provider submits an implant log. The Phia Group has seen an itemized billing with a single line item called "ortho implant, miscellaneous" and there was a unit number of "1;" however, when we requested the implant log, we discovered that there were 11 implants that were being billed. Ironically, the provider billed for every tab of Tylenol (billed at $6.40 each), but did not provide itemized detail of the $35,000 implant charges. The implant log (or better yet, the cost invoice) is a critical component for high-dollar implant claim review. The request for the implant log may bump up against some network contracts, but there is an argument to be made that even an otherwise accurate standard itemized bill is not actually completed without the implant log, which provides make, model, and SKU of the implants.

Proactive Contracting

As shown, the market is clawing for a piece of this billion dollar industry and so there may be valuable deals to be struck in your local market. ASCs present an interesting option for healthcare payers as they arguably offer better quality and value than the one stop shop model of larger hospital systems, which can feel like a maze at times to consumers. As such, it makes sense to explore these options for direct contracting and creating member incentives for using the lesser known facilities. Lastly, many of these facilities are open to discussing bundled pricing. At The Phia Group, we are seeing many of our clients having success with this strategy.

Ad Hoc Negotiations

What do you do if you have a claim with high dollar implant charges? The first consideration is whether it is INN or OON. If it is INN, you must review the payer access agreement to see what options the contract allows for claim review and negotiations. Some PPO contracts have soft-spots whereas others are virtually iron-clad in preventing any additional cost-containment. That is not to say that there are

not options if the contract is a challenge; it just means that your odds of success are admittedly lessened.

That said, no matter how good or flexible the PPO agreement is; if the SPD language isn't good, then it doesn't matter anyway. The default is that billed charges are to be paid in full; only the SPD can prevent that. The final consideration is cost data on the implants, which can be difficult to acquire, and providers will typically not disclose their costs by sending their cost-invoices. Remember that there is no fixed price for implants; there are a range of acquisition costs which must be considered. For this reason, payers must find data solutions or an expert partner if they want to be on equal footing with the provider for a settlement discussion.

Conclusion

In the absence of meaningful regulation on implant charges, payers are left with the burden to attempt to control their own implant cost burdens. As shown, this can be achieved through thoughtful plan design, consumer engagement and education, savvy contracting, and strong claim review and negotiations. With proper measures in place, self-funded payers and their administrators can protect themselves from predatory billing practices and re-invest the savings into the health and wellbeing of their members.

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