Magellan Healthcare Specialty Trends

2022

Magellan HEALTHCARE®

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Radiology

Artificial intelligence in radiology: Current trends and reimbursement

Artificial intelligence (AI) refers to computer algorithms that can mimic the characteristics of human intelligence, such as problem solving and learning. AI in radiology has been gaining ground in clinical practice and is being incorporated into daily practice in a variety of ways, including large vessel occlusion, intracranial hemorrhage (ICH), and pulmonary embolism to name a few.

Historically, AI software was not widely used in radiology because many false-positives led to clinician distrust. Despite technological advances, trust issues remain, exacerbated by radiology rarely being black and white. Additionally, it is common for radiologists to assess various factors before reaching a "final" impression of images (and that impression may also have a level of uncertainty).

The aim of AI software is to help reduce interpretation errors and increase confidence in interpretations. However, some AI models can introduce greater uncertainty in the interpretation process, especially if the software's interpretation of the scan is discordant with the radiologist's initial interpretation.

Who will pay for AI?

There is no clear indication how this technology will be paid for and ultimately reimbursed by payers. Currently, approximately 21 radiology-related medical devices and algorithms have been approved by the U.S. Food and Drug Administration (FDA). More importantly, the Centers for Medicare & Medicaid Services (CMS) recently approved reimbursement for these FDA-approved AI devices and algorithms via the Medicare Coverage of Innovative Technology pathway, which consists of two possible routes for reimbursement. Payment may come through the Medicare Physician Fee Schedule (MPFS) or the Inpatient Prospective Payment System (IPPS). If the MPFS route is chosen, the reimbursement mechanism would be the Current Procedure Terminology (CPT®) codes, which are maintained by the American Medical Association. If the IPPS route is chosen, the Diagnosis Related Groups (DRGs) and New Technology Add-on Payment (NTAP) will be the mechanism for reimbursement.

The IPPS pathway

In September 2020, CMS granted reimbursement for Viz.ai's Viz LVO (formerly known as ContaCT), AI-driven triage software for large-vessel occlusion, through the NTAP pathway. Since CMS' approval of Viz LVO for NTAP, other large-vessel occlusion AI software developers, such as RapidAI, Aidoc and Avicenna.AI, have applied for NTAP status from CMS. The NTAP program was initially introduced in 2001 with the intent to help provide support for up-and-coming medical therapies for patients enrolled in Medicare. To be approved for the NTAP program, the following criteria must be met:

1. The proposed technology must be new (<3 years old) and not based on another technology.
2. The proposed technology is not currently covered under the existing DRG.
3. The proposed technology must demonstrate a considerable advantage over already covered technologies (i.e., outcome data).

To share the financial risk between Medicare and hospitals providing these new technologies, CMS increased payment to 65% of the lesser of (1) the cost of the new medical service or technology or (2) the amount by which the costs of the case exceed the standard DRG payment.

IPPS is only available for three years, and it remains unclear if CMS will make DRG adjustments for these approved new technologies. CMS has historically lowered NTAP reimbursement following the initial year of approval. A critical point to remember is one of the criteria to be approved via the NTAP pathway is the technology must not substantially duplicate existing technologies. This raises the question of whether CMS will consider additional AI-driven algorithms that improve workflow a new technology and grant approval through the IPPS pathway.

The MPFS pathway
In 2020, CMS finalized a new ophthalmology CPT code, IDx-DR, the first of its kind for AI. IDx-DR uses AI to analyze retinal camera images for diabetic retinopathy screening. The relative value unit of this AI code/reimbursement is based on its ability to function independently without physician input (CPT code relative value units are based on two major components, physician work and practice expense.). In significant contrast, AI in radiology is mainly considered a support function to the radiologist instead of wholly independent. Whether the IDx-DR CPT code can be applied similarly to radiology or more along the lines of normal work for a specific procedure remains to be determined. Furthermore, in radiology, AI algorithms may ultimately result in more physician time, like what occurred with computer-aided detection in mammography.

Future payment alternatives
As healthcare shifts to a value-based payment system, AI may serve as a valuable tool for radiologists and imaging reimbursements. An example of this is the Merit-based Incentive Payment System model, which is the predominant pathway through which radiologists are reimbursed. Another possibility is an alternative payment model where AI algorithms could predict future disease risk based on imaging examination results. This could decrease overall cost of care and improve patient outcomes, leading healthcare systems to reimburse for this type of tool.

AI and large vessel occlusion strokes
The first AI product to be approved via the NTAP program for large vessel occlusion (LVO) strokes was Viz LVO. Since the 2018 FDA approval of the Viz LVO software to aid in the detection of LVO strokes, several studies have demonstrated improved triage of patients with LVO strokes with resultant improved patient outcomes and reduced length of stay.

Strokes are the number one cause of long-term disability in the United States. Treatments such as endovascular thrombectomy/thrombolysis for LVO strokes are effective, but they are time sensitive. The Viz LVO software automatically analyzes computed tomography angiography (CTA) of the brain of patients suspected of stroke to identify LVOs. Scans enter the radiologist's queue for reading and are simultaneously processed by the AI software. If an LVO is detected by the AI software, that study is flagged for the radiologist and sent directly to the on-call stroke team, allowing them to make a treatment decision or guide the team to further investigate. This alert has resulted in an average 52-minutes faster diagnosis than current practices.

AI and stroke: Is AI noncontrast computed tomography comparable to magnetic resonance imaging?
Magnetic resonance imaging (MRI) with diffusion-weighted sequences is considered the reference standard in evaluating for early ischemia. However, the lack of availability of MRI is a limitation. As computed tomography (CT) is often readily available and takes less time to image, it has become the standard imaging modality when evaluating acute cerebral ischemia. One critical limitation of CT, when contrasted with MRI, is the estimation of the degree of infarction on CT as the density variations of the involved brain parenchyma can be very subtle and could be further complicated by prior vascular lesions as well as normal variants. Such subtle changes are often not appreciated by the human eye. A recent retrospective study by Qiu et al trained the AI system on patients who had both an MRI and CT (within 1 hour of each other) using the diffusion MR images to train the CT-based AI. They subsequently tested another set of CT scans with the trained AI model and compared them with diffusion MRI and found that machine learning software can identify subtle changes and patterns on CT with high accuracy. As such, noncontrast-enhanced CT scans of patients with acute ischemic stroke aided with this AI technology may ultimately rival information obtained with either CT perfusion or MRI. The study concluded that the AI software algorithm demonstrated promise in not only identifying, but also measuring, infarction on baseline noncontrast-enhanced CT scans and could transition into the clinical realm.

AI and cerebral hemorrhage
Considered the standard of care in the assessment of acute stroke and head trauma, noncontrast CT of the head is the most common emergent imaging study requested for neurological conditions. In trauma patients as well as those at risk for an acute stroke prior to thrombolytic use, early diagnosis of acute intracranial hemorrhage is critical for improving patient outcomes. Radiology-support AI systems can evaluate head CT studies within seconds of its

completion and immediately flag hemorrhages to alert radiologists or other clinicians (e.g., trauma or stroke teams), and to reprioritize the interpretation of the exam.

In preliminary studies, the software showed similar accuracy to interpreting radiologists in identifying hemorrhage type, precise localization, and hemorrhage volume, allowing accurate assessment for interval changes on follow-up studies. This technology has been explored and utilized in small sizes in outpatients with significant benefit. Arbabshirani et al demonstrated an AI algorithm can successfully prioritize radiology worklists to reduce time to diagnosis of new outpatient ICH by 96% (from 512 to 19 min) and may also identify subtle ICH overlooked by radiologists.

Can AI help in the diagnosis of pulmonary embolism (PE)?
The diagnosis of PE is multifaceted, utilizing clinical presentation, D-dimer testing, and imaging. Studies have shown the earlier a PE is identified, the better the patient's outcome. Weikert et al found the AI algorithm in their study correctly identified 215 of 232 exams positive for PE (sensitivity 92.7%, 95% confidence interval (CI)), and 1,178 of 1,233 exams negative for PE (specificity 95.5%; 95% CI). The false-positive scans encountered were contrast agent-related flow artifacts, pulmonary veins, and lymph nodes. In a more recently published retrospective study, Ben Cheikh et al utilized an AI algorithm approved by the FDA and European Conformity and found the AI algorithm detected 219 suspicious PEs, of which 176 were true PEs, including 19 true PEs missed by radiologists. The study also noted the accuracy, specificity, and positive predictive value were significantly higher for radiologists compared with the AI, except in the subcohort of scans with poor-to-average contrast bolus quality, which is typically challenging for radiologists. The authors concluded the AI algorithm best served as a safety net, or second look, in emergency radiology practice due to high sensitivity and negative predictive value; thereby, increasing the self-confidence of radiologists. Furthermore, several studies have shown that AI utilization in CTA PE exams help clinicians to automatically prioritize exams with a high suspicion of PE and may serve as a secondary reading tool.

Conclusion
AI software is ubiquitous in life, and other industries have already used this technology under the watchful eyes of human operators. As the research and deep machine learning continue to evolve, application in various aspects of healthcare is almost certain. Magellan Healthcare will continue to review AI software and other technologies as they continue to advance, as well as reimbursement patterns, to reduce diagnostic errors to the greatest extent possible.

References

iSono Health wearable 3D breast ultrasound

The FDA recently approved an automated whole-breast ultrasound system and intuitive software for image acquisition and analysis. The 3D breast ultrasound unit can automatically scan and analyze the entire breast in under two minutes. This unique system does not require a trained sonographer and allows for 3D visualization of the breast tissue. Breast ultrasound is a useful adjunct to mammography to improve breast cancer detection in women with dense breasts. This system has the potential to improve breast cancer screening worldwide, especially in countries with limited resources. Currently, iSono Health is conducting prospective case studies to validate the deep learning software that aids clinicians in localization and classification of breast lesions. This up-and-coming technology made for point-of-care physicians should be watched as it could potentially be performed during an in-office visit by a breast surgeon or gynecologist.

References

Radiomics

While in its early stages, radiomics deals with the mining of quantitative textural information for tissue characterization from medical images in a specific region of interest (ROI) that is not visually detectable by radiologists using advanced mathematical analysis. Utilizing a mathematical analysis of the gray-scale pattern, spatial distribution of signal intensities, and pixel interrelationships in the ROI, radiomics can quantify underlying textural information on the images and has the potential to act as a "virtual biopsy." Radiomics, in contradistinction to standard biopsies, can analyze the whole tumor (rather than a focal area) and can be applied at various time points for disease monitoring, offering potentially important diagnostic information related to disease evolution. This diagnostic information can then be combined with other patient characteristics and other clinically available information to develop a more patient-tailored treatment approach. For example, research has shown radiomics analyses can distinguish prostate cancer from benign prostate tissue and even add information about prostate cancer aggressiveness. Radiomics in the evaluation of lung cancer and glioblastoma multiforme (a malignant tumor affecting the brain or spine) has demonstrated it can be an adjunct to assess patient prognosis.

How does the process work?

1. Images are acquired on standard imaging units (e.g., MRI, CT, positron emission tomography (PET)).
2. The radiologist analyzes the image and selects the ROI of the sample. (While most ROI identification is performed manually by a radiologist, it can be automated with segmentation software.)
3. Radiomic features of the ROI are extracted based on the texture and shape properties from the images. Lastly, mined data points are sorted (e.g., distinguishing malignant tumors from benign tumors, metastatic potential or survival expectations) into a report.

Radiomics can be applied to almost all imaging modalities, including radiographs, ultrasound, CT, MRI, and PET studies, and can integrate across modalities using the potential compounded additive value. Most of the work in radiomics has been in the oncology realm, but potentially can be applied to any disease. For example, in breast cancer, multiple studies have been conducted using radiomic analysis to differentiate between benign and malignant breast tumors, classify histological types of invasive breast cancer, and predict chemotherapy response in breast cancer patients. Furthermore, several articles have detailed the use of radiomics to predict axillary lymph node metastases in breast cancer patients. Several small studies have explored radiomics in esophageal, prostate, and colorectal cancers, as well as differentiating malignant from benign adnexal lesions on MRI. As the field of radiomics matures, radiological reports will also evolve into mineable patient-specific imaging biomarkers, creating a tailored approach to patient care. Magellan Healthcare will continue to monitor this field as it continues to evolve in both the oncologic and non-oncologic settings.

References

Tracer on the horizon: Gallium 68-labeled fibroblast activation protein inhibitor PET imaging

Gallium 68 (68Ga)-labeled fibroblast activation protein inhibitor (FAPI) PET imaging, an up-and-coming tracer, is being studied in a variety of malignancies (e.g., pancreatic cancer, esophageal cancer, non–small cell lung cancer, head and neck cancer, and colon cancer).

Fibroblast activation protein (FAP) is overexpressed in cancer-associated fibroblasts, resulting in its use as a target for therapeutic agents. While 18F-fluorodeoxyglucose (18F-FDG) accumulates in areas of acute inflammation, FAP uptake is prototypical in areas of chronic inflammation where a fibrotic reaction has been followed by tissue remodeling. 68Ga-FAPI is independent from blood sugar levels, thereby needing no dietary preparation prior to imaging. Additionally, 68Ga-FAPI has a relatively short tumor uptake, at approximately 10 minutes after injection, which could

also avoid the one hour uptake rest time required before imaging with 18F-FDG. With these exciting parameters, 68Ga-FAPI PET could simplify the clinical workflow with shorter waiting and scan times compared with FDG-PET. The use of 68Ga-FAPI PET could also be expanded to patients with uncontrolled diabetes where standard FDG-PET may be non-diagnostic due to FDG redistribution. Initial literature notes a relatively short half-life of 68Ga-FAPI, which makes it impractical for institutions without a nuclear pharmacy; however, 18F-FAPI agents are in development to allow for more flexible scanning with a longer half-life.

Initial studies using 68Ga-FAPI tracers demonstrate the malignancies with the highest standardized uptake value (SUV) are lung, breast, and esophageal cancers; cholangiocarcinoma; and sarcomas. These malignancies currently face limitations with 18F-FDG PET/CT, which potentially opens indications for 68Ga-FAPI PET/CT in the future. 68Ga-FAPI PET has a significantly lower hepatic background for 68Ga-FAPI (SUV 1.7) than for 18F-FDG (SUV 2.8), which may be advantageous for liver metastasis detection. While 68Ga-FAPI PET/CT and 18F-FDG PET/CT have similar results in detecting primary tumors and metastasis in the lungs, 68Ga-FAPI is superior in detecting brain and bone metastases, potentially decreasing the need for a dedicated brain MRI during staging. For tumor entities known to perform poorly with 18F-FDG, such as hepatocellular carcinoma or pancreatic cancer, 68Ga-FAPI PET/CT may be considered complementary, demonstrating intermediate uptake. Since the radiotracer uptake is seen in areas of chronic inflammation where there has been a fibrotic reaction and resultant tissue remodeling, such as in myocardial infarctions, this tracer could play a complementary role to 18F-FDG in the future for cardiac diseases as well.

Multiple small studies and case reports document the potential utility of 68Ga-FAPI in various malignancies. Magellan Healthcare will continue to monitor the literature for larger multi-institutional studies and changes in the society guideline recommendations.

References

Lutetium Lu 177 vipivotide tetraxetan (PLUVICTO™) radioligand therapeutic: A new treatment for prostate cancer

PLUVICTO is a new therapy for patients with prostate specific membrane antigen positive (PSMA+) metastatic castrate-resistant prostate cancer (mCRPC). Regardless of the location of metastasis, this therapy works by precisely delivering radiation to PSMA+ tumor cells. PLUVICTO is given weekly over a six-week period. The current application of PLUVICTO is for use in mCRPC patients resistant to androgen receptor directed inhibition (ARDI) and taxane-based chemotherapy.

PLUVICTO is a radioligand, made up of two parts: a ligand and a radioisotope (DOTA chelator radiolabeled with lutetium-117). The ligand finds and specifically binds to the cancer cells that have PSMA, and the radioisotope emits therapeutic radiation to those cells (PSMA+ prostate cancer cells). Unlike many other therapies, PLUVICTO can deliver radiation in a more precise manner to prostate cancer cells found throughout the body by finding PSMA+ cells, binding to them, then delivering radiation regardless of the cell's organ location.

PLUVICTO was approved March 23, 2022 by the FDA after clinical trials showed improved outcomes for patients with mCRPC who have failed other treatments, including ARDI and taxane-based chemotherapy. In the study (VISION trial), patients were randomized to PLUVICTO plus best standard of care (BSoC) or BSoC alone. The study showed statistically significant improvements in overall survival, overall response rate, imaging-based progression-free survival, and improved time to symptomatic skeletal event or death in patients who received PLUVICTO plus BSoC. Some patients in the PLUVICTO plus BSoC subgroup obtained a complete response; whereas, no patients in the standard of care subgroup exhibited a complete response.

Currently, phase III clinical trials are underway to determine the effectiveness of PLUVICTO administered earlier in the treatment pathway, which has the potential to shift the paradigm for the treatment of prostate cancer. New radioligand agents, such as PSMA (Lu-177)-PNT2002 (POINT Biopharma), are also on the horizon.

Magellan Healthcare implemented the use of PSMA PET (using Ga 68 PSMA-11 or piflufolastat F 18 (Pylarify®)) for prostate cancer for 2022. Based on current recommendations, we will be adding Ga 68 gozetotide (Locametz®) and incorporating PSMA PET prior to and following treatment with agents such as PLUVICTO in 2023.

References

Cardiology

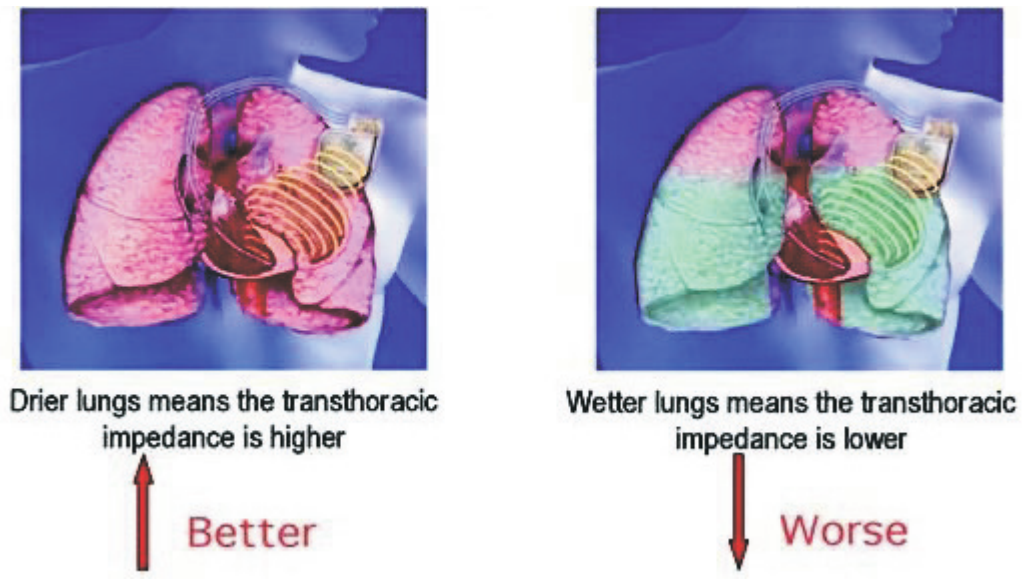
Trends in heart failure monitoring

Heart failure (HF) is a large, growing public health problem world-wide. In the United States, an estimated six million patients carry a diagnosis of HF, including HF with reduced left ventricle ejection fraction and HF with preserved ejection fraction. The number of HF patients is expected to double by 2030. Readmission for HF is associated with poorer patient outcomes in terms of morbidity and mortality, and rates continue to be a major problem. At $30 billion annually, the financial burden to the U.S. healthcare system is also large. Reasons for high readmission rates for HF include lack of access to timely outpatient follow-up, poor patient compliance with diet and medications, and the progressive nature of the disease.

By the time HF symptoms develop, it is often too late to avoid an admission to the hospital. Strategies have been developed to try to detect signs of HF decompensation before symptoms develop. These include the use of frequent nurse telephone visits, as well as remote monitoring of patient vital signs, particularly daily weight. Increasing weight can be used as a marker of increasing fluid volume (fluid retention). When increasing weight is detected, the patient is advised to adjust medication and reduce sodium in the diet to prevent the development of HF symptoms and ideally prevent hospital admission. This method has had some success but is still limited by the fact weight gain is a relatively insensitive and non-specific means of monitoring volume status. Also, by the time weight gain is detected, significant HF decompensation may have already occurred. Patient compliance is also required because the patient must obtain their weight and other vital signs themselves and transmit the data to a monitoring center.

More advanced remote monitoring, possibly offering earlier detection of HF decompensation with less reliance on patient involvement, is made possible in patients with implanted devices such as a cardiac defibrillators (ICD) or cardiac resynchronization devices (CRT). These devices have the capability of monitoring volume status by measuring thoracic impedance. Basically, the idea is as fluid accumulates in the lungs (such as in HF exacerbation), it acts as a better conductor of electrical current generated by the ICD or CRT. As a result, thoracic impedance decreases as depicted in figure 1 below.

Figure 1: Impedance change as measured by the device is both directly and inversely related to fluid accumulation in the lungs (Ref. 46)



Thoracic impedance changes may occur earlier during HF decompensation than noticeable weight gain and before symptoms develop. Thoracic impedance can be automatically measured several times per day and the data transmitted to the provider who can then contact the patient and advise adjustment in medical therapy.

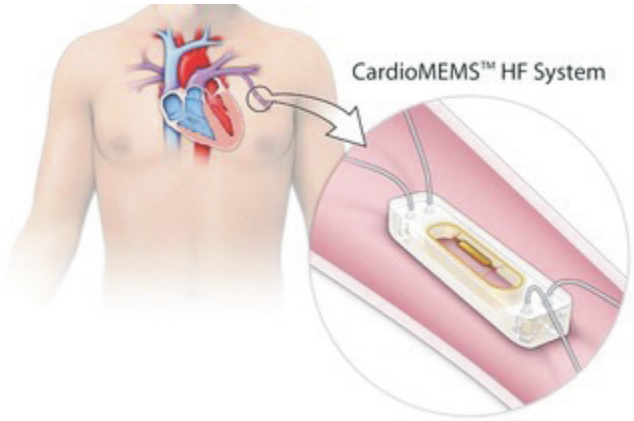
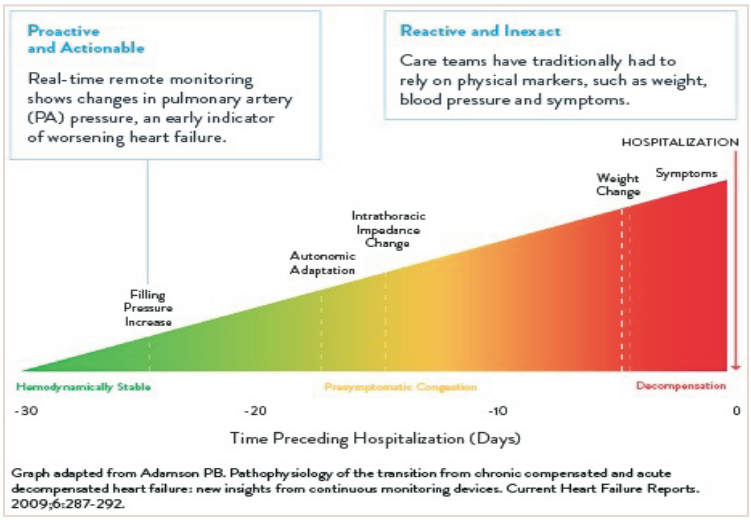


Figure 2: Implantation of CardioMEMS (Adapted from Ref. 47)

A wireless, implantable real-time monitor called CardioMEMS™ was FDA-approved in 2014. The device (figure 2) is the size of a paper clip and is implanted in a pulmonary artery using a catheter threaded through a vein in the leg. CardioMEMS measures pulmonary artery pressure, with rising pressure corresponding to fluid retention. The device is expected to last for the life of the patient.

Figure 3: Monitoring early indicators of HF greatly decreases HF hospitalization rates (Ref. 49)



Graph adapted from Adamson PB. Pathophysiology of the transition from chronic compensated and acute decompensated heart failure: new insights from continuous monitoring devices. Current Heart Failure Reports. 2009;6:287-292.

Rising pulmonary artery pressure can be a sensitive indicator of increasing intravascular volume. This implantable monitor provides the advantage of early detection of HF decompensation. As noted, this information is gathered in real time. The data is then automatically transmitted from the patient's home to the provider, allowing for timely intervention, such as medication adjustment. A recent study presented at the American College of Cardiology's Annual Scientific Session demonstrated a 58% reduction in HF admission for patients implanted with this device. These results were further supported by the one-year outcomes report of an ongoing multiyear, multicenter study showing a statistically relevant decrease in HF hospitalization rates post-implantation.

References

Interventional Pain Management

The field of pain management is moving away from opioid therapy, focusing on precise interventional options to treat complex chronic pain syndromes instead. As a result, the identification of peripheral neuropathies has come to the forefront with how they play a significant role in a patient's chronic pain etiology and therapies that will provide safe and effective pain relief as new, emerging topics.

Genicular nerve block/radiofrequency ablation

Genicular nerve blocks and genicular neurotomy are treatments of the sensory nerves that supply the knee and help improve pain related to osteoarthritis. The genicular nerve branches are the nerves in the superomedial, superolateral, and inferomedial quadrants located near the periosteum. These treatments have been successful in helping patients obtain improved function and pain control when severe knee joint pain has been unresponsive to medical and surgical management or when they are unable to tolerate medical or surgical interventions due to coexisting comorbidities. Peer-reviewed medical literature has identified studies' lack of adequately designed trials concerning the use of genicular nerve blocks and radiofrequency ablation (RFA) as treatments for chronic knee pain. A systematic review of randomized controlled trials (RCTs) showed general agreement that RFA had a benefit on pain, function, and composite scores compared to the control treatments at 3- and 6-month follow-up.

References

Cluneal nerve blocks

Cluneal nerve block (CNB) is a specialized treatment method that effectively reduces chronic pain in the lumbar to sacral region of the back. While seen as a therapeutic tool, CNB can also be employed as a diagnostic technique due to its dual purpose of relieving pain and identifying the true cause of said pain. Cluneal nerve entrapment (CNE) is often underdiagnosed and may cause pain in the sacral region. A successful CNB indicates that CNE is responsible for a patient's chronic pain. Some patients can avoid surgery if they receive CNB therapy.

CNB has been gaining popularity over the past decade with the advancement of ultrasound application and peripheral nerve stimulation (PNS). Roughly 10% of chronic low back pain is related to cluneal neuralgia, which is repetitive friction of the superior cluneal nerve under the thoracolumbar fascia, or rarely constriction in the osteofibrous tunnel. With this ever-growing popularity, CNB could become a standard of care due to the success PNS therapy can offer to patients.

References

Peripheral nerve stimulation

Implemented more variably, peripheral nerve stimulation (PNS) can be used to treat a variety of chronic peripheral neuropathic pain. Past uses of PNS were disregarded due to the invasiveness of the process; however, recent advances have made it an appealing option for patients with specific chronic refractory neuropathic pain conditions.

PNS is effective if a patient has one of the following:

1. Occipital neuralgia
2. Chronic knee and shoulder pain
3. Intercostal neuralgia
4. Chronic lower back pain
5. Nerve pain from peripheral nerves in the upper or lower extremities

Studies show 42% of people tested for the socioeconomic benefit of PNS are positive as indicated by the individual either returning to work, increasing reported confidence/productivity at work, or consistently working before and after implantation. Ultimately, PNS therapies are safe and reversible, but further RCTs are needed to decipher the implications of percutaneous PNS in pain management.

References

Orthopedics

Balloon spacer for irreparable rotator cuff tears

Rotator cuff tears are one of the most common orthopedic conditions. While some tears are traumatic, most are degenerative, the incidence of which increases with each decade of life. With large rotator cuff tears, the function of the tendons to suppress the humeral head during overhead movements is lost, and the humeral head is pushed up against the acromion, producing pain and loss of function.

Many rotator cuff tears can be treated with non-operative modalities, such as rest, activity modification, physical therapy, medication, etc. However, for those patients for whom conservative management fails, a variety of ways to repair the rotator cuff is available. Smaller tears can usually be surgically managed by direct repair; however, many large rotator cuff tears are deemed irreparable and present a considerable challenge. Irreparable tears might be those that show fatty infiltration and muscle atrophy, or superior migration of the humeral head with a narrowed or absent acromiohumeral interval.

Even with advances in surgical technique and improved technology, failure rates following rotator cuff surgery for these large tears are high. No one surgical technique is superior to another; each has many pros and cons. For large or massive rotator cuff tears that are deemed irreparable, the following options might be considered:

- Partial repair
- Tendon transfers (latissimus dorsi or lower trapezius)
- Debridement
- Subacromial decompression
- Biceps tenotomy or tenodesis
- Superior capsular reconstruction
- Hemiarthroplasty
- Reverse total shoulder arthroplasty

Stryker (InSpace Balloon) has developed a relatively new procedure for irreparable rotator cuff tears where a balloon spacer implant is arthroscopically inserted into the subacromial space. In general, the procedure is indicated for low-demand patients over 65 with irreparable rotator cuffs tears associated with mild to moderate glenohumeral arthritis and for some patients that would benefit from a less-invasive procedure with shorter operative times. The balloon is made of a polylactide/ϵ-caprolactone copolymer believed to biodegrade within 12 months. The saline-filled "balloon" can improve function and reduce pain by decreasing humeral head contact with the acromion as it lowers the humeral head to a more anatomic position and provides more leverage to the deltoid muscle for overhead movements. The device is designed to serve as a physical barrier to reduce subacromial friction and to restore proper shoulder biomechanics by lowering the humeral head closer to a more normal position against the glenoid cavity during movement.

Surgical technique

The diagrams below (adapted from ref 68) outline the surgical technique.

Figure 1: Diagram of massive rotator cuff tear

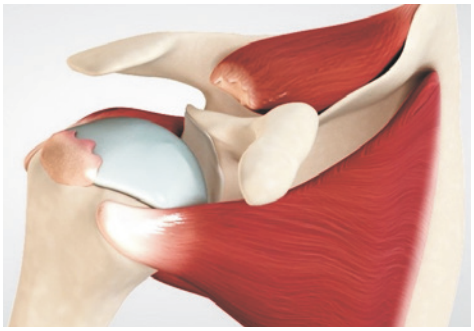


Figure 2: Sizing of the subacromial space determines size of balloon implant

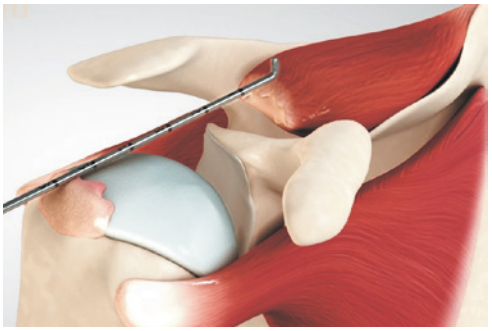


Figure 3: Insertion of the balloon deployment device

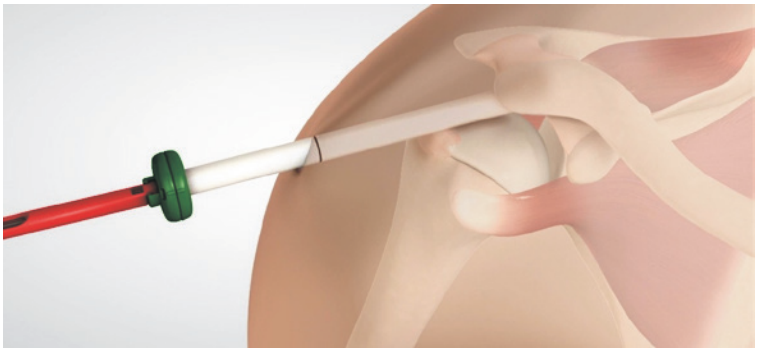


Figure 4: Saline-filled balloon is inflated

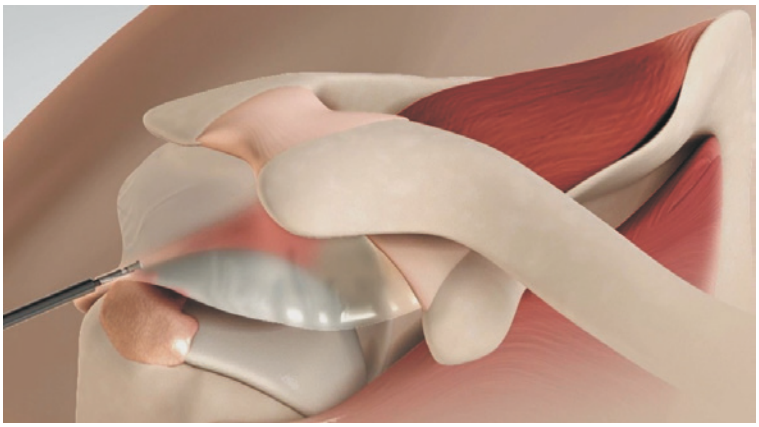
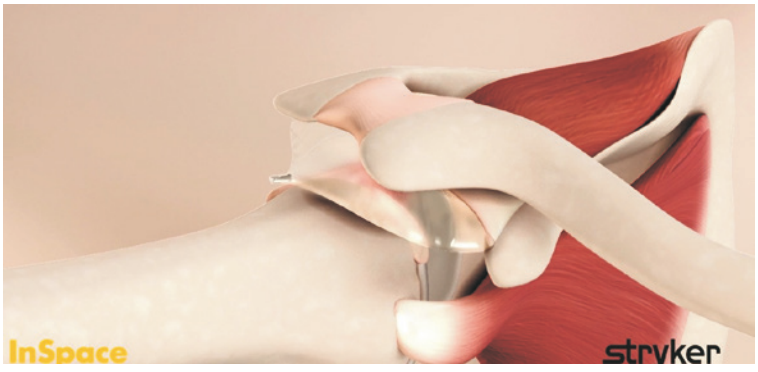


Figure 5: The balloon spacer provides a barrier against friction with the shoulder abducted



Because of the minimally invasive nature of the balloon spacer and modest success rate of the alternative complex surgical procedures, there is currently considerable interest in this procedure from the orthopedic community. While initial studies are promising, prospective comparative long-term studies will be required to determine clinical outcomes, such as pain relief and improvement in function, and to determine if any ill-effects or complications are occurring. As new literature emerges for the InSpace balloon spacer, Magellan Healthcare will continue to monitor it and will rereview the findings as part of our annual review cycle.

References

Detrimental effects of intra-articular cortisone injections

Cortisone, a potent anti-inflammatory agent commonly given as an intra-articular injection for hip, knee, or shoulder arthritis, is also commonly given for impingement or rotator cuff problems of the shoulder. Its function-improving and pain-relieving properties are well-documented. Unfortunately, these injections are not without risk, especially as it pertains to subsequent surgical procedures, such as arthroscopy and arthroplasty. Current literature has demonstrated an increased risk of infection when these injections are given within 12 weeks of a joint replacement of the hip, knee, or shoulder. This increased risk of infection is thought to be secondary to the immunosuppressive effect of the intra-articular cortisone.

Although some studies contradict this cortisone-infection association, many of these were underpowered series with small patient populations. Because of the strength of existing studies that do show an increased risk of infection when an arthroplasty has been preceded by an intra-articular cortisone injection, Magellan has adopted the conservative approach to this, and all requests for total joint arthroplasties preceded by a cortisone injection within 12 weeks of surgery will be denied and are listed as a contraindication in our guidelines:

1. Guideline Number: NIA_CG_313 - HIP ARTHROPLASTY
2. Guideline Number: NIA_CG_315 - KNEE ARTHROPLASTY
3. Guideline Number: NIA_CG_317 - SHOULDER ARTHROPLASTY

Also, recent studies indicate an increased risk of infection even when arthroscopic surgery of the knee has been preceded by a cortisone injection. This is quite remarkable when one considers the already low infection rate of these minimally invasive procedures that utilize small incisions and copious amounts of irrigation fluid throughout the procedure. With regards to cortisone injections prior to a rotator cuff repair, not only is the risk of infection increased but the failure rate also increases. Because of these associations, the 2023 guidelines for arthroscopic surgery of the knee and shoulder will list cortisone injections within 4 weeks of a knee arthroscopy and within 12 weeks of a rotator cuff repair as a contraindication for surgery:

1. Guideline Number: NIA_CG_316 - KNEE ARTHROSCOPY
2. Guideline Number: NIA_CG_318 - SHOULDER ARTHROSCOPY

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Spine Surgery Trends

Outpatient surgery

The migration of procedures to the outpatient setting continues in spine surgery with advances in technology and surgical technique continuing to create the opportunity for traditional inpatient procedures to be performed in the outpatient setting. This change continues to be driven by patients, surgeons, and payers. Improved experience, increased efficiency, and lower cost will continue to fuel this trend into the foreseeable future.

Technology

Technology in the operating room continues to advance. Over the next several years, three areas of innovation are expected to enhance how surgeons plan and perform complicated spinal reconstructive procedures: robotics, augmented reality, and AI. Robotics has been used in surgery for many years and is still considered to have tremendous potential for growth in the areas of neural decompression and complex implant placement. Augmented reality uses a portable headset to overlay a hologram-like reconstruction of the spine to enhance what the surgeon sees intraoperatively, allowing for safer placement of instrumentation. This has been compared to having your surgeon wear an Iron Man helmet. AI uses data and predictive analytics in the planning and execution of surgery, leading to improved surgical outcomes. Overall, these technologies allow for more minimally invasive surgical techniques that reduce complications and accelerate patient recovery.

Underperforming procedures

Sometimes marketing and hype surrounding new technology outpaces science, and the hope of improved patient outcomes never materializes. Two relatively recent examples include laser spine surgery and interlaminar/interspinous devices. Laser spine surgery was initially touted as being the most advanced treatment available for spinal stenosis and herniated discs. A recent study in the Journal of the American Academy of Orthopaedic Surgeons found the risk associated with lasers far outweighed the potential benefits. Interspinous and interlaminar devices were initially considered an innovative technology for treating lumbar spinal stenosis. These devices have largely failed to live up to their hype and have not created sustained improvement of neurogenic pain. As new technology comes to market, we must be sure to balance the hope and hype with real science and allow the evidence to speak for itself.

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Physical Medicine Trends

Mobile digital devices provide affordable augmentative and alternative communication alternatives

An electronic augmentative and alternative communication (AAC) system is a speech generating device used to supplement or replace speech or writing for individuals with severe speech impairments, enabling them to verbally communicate. AACs are considered durable medical equipment and cost up to $14,000. Since AACs are dedicated devices, they can only be used for communication purposes. They can come equipped with the ability to scan pictures for individuals who cannot touch a screen with precision or a special camera that enables eye gaze selection. For many, these devices have been difficult to obtain without proper funding.

The iPad®, invented as a consumer mobile digital device for work and entertainment purposes, has revolutionized the market. These mobile digital devices, or tablets, were not initially considered for use as speech generating devices as many wondered why children would be motivated to use it as a speech device if they could access games and videos with it. Also, only one or two communication apps were originally available, eliminating it as a one-size-fits-all option. Moreover, the device initially lacked the ability to be modified for adaptive switches (such as large buttons or pads which allow users to select with a touch of the wrist, elbow, hand, etc.)—an important feature for individuals with physical disabilities who may lack the motor control to use their finger to select a picture on a speech device or tablet. For people who needed access to language and were able to touch a screen (use direct access); however, it has brought affordability, something AAC systems previously lacked.

Over the past few years, communication apps and modifications for the iPad and other mobile digital devices have increased exponentially. Many speech therapists realized the personal tablet is a viable option for an AAC device, and now hundreds of apps are available in various robust language systems. Case options help address portability and durability, and different screen sizes are available. A mobile digital device can be locked into an AAC app and dedicated to communication.

Recently, Ablenet® developed Blue2 Bluetooth Switch, a wireless adaptive switch that syncs with devices, such as e-readers and iPads, allowing direct access for selection of a picture for users who are unable to touch the screen. Other companies are bundling tablets, cases, and AAC apps, which many insurance plans cover. The average cost of an iPad is approximately $500. A communication app, such as the Proloquo2go ($169), can have a default vocabulary of over 7,000 items, and is fully expandable and easy to install and use. Other apps can cost less but have limitations, such as costly additional features in the app, reduced picture capacity, subpar illustrations, and limited number of preloaded buttons. Schools are buying tablets and apps as an affordable option for students needing a device in the school setting. Dedicated AAC manufacturers have also entered the niche marketplace by modifying tablets with pre-loaded software apps and cases that can be mounted on a wheelchair. These packages cost much less ($2,000-4,000) than the full-sized AAC devices.

The use of tablets has revolutionized the AAC industry in just a few years, and people with severe speech impairments are reaping the benefits of their portability, affordability, and functionality.

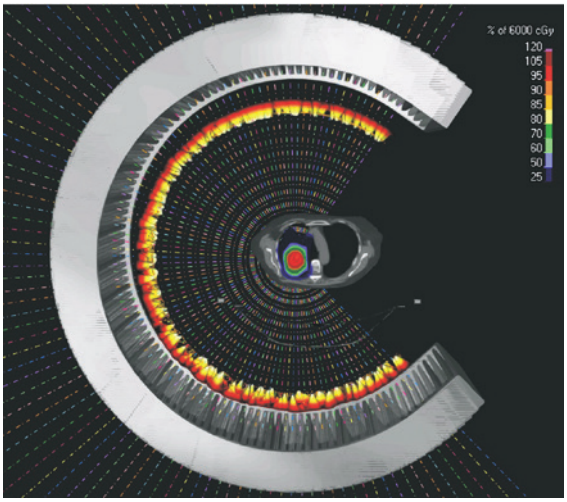
References

Radiation Oncology

Spot-scanning proton arc therapy

Passive-scattering has been replaced with pencil-beam scanning, and now rotational proton arc therapy is being developed. The current intensity modulated proton therapy technique uses only a limited number of treatment fields. Proton arc therapy, an advanced radiation therapy technique, consists of a continuous delivery of a proton beam as the gantry rotates around the patient (Fig. 1). During this rotation, the beam energy and intensity are adjusted to confer higher conformality to the tumor, more efficient delivery, and increased plan robustness.

Figure 1: Gantry rotation saves time in clinic (ref. 104)



Stereotactic MRI-guided adaptive radiotherapy

Over the past 30 years, conventional image-guided radiation therapy has introduced many lifesaving developments, yet poor soft tissue contrast. Combining the latest innovations in precision radiation delivery with groundbreaking magnetic resonance image guidance and on-table adaptive therapy is the next big advance in radiation oncology.

ASTRO issues clinical guideline on external-beam radiation therapy for primary liver cancers

A clinical guideline from the American Society for Radiation Oncology (ASTRO) provides guidance on the use of radiation therapy to treat adult patients with primary liver cancers using external-beam radiation therapy (EBRT). Evidence-based recommendations outline indications and optimal EBRT dosing, as well as techniques and treatment planning for patients with hepatocellular carcinoma and intrahepatic cholangiocarcinoma, with a strong emphasis on multidisciplinary care. The guideline, ASTRO's first for primary liver cancers, was published by Apisarnthanarax, et al in Practical Radiation Oncology.

Using artificial intelligence to help cancer patients avoid excessive radiation

Recently, the Journal of the National Cancer Institute published a study by a group of researchers from Case Western Reserve where AI was used to identify individuals (n=439) with human papillomavirus (HPV)-associated oropharyngeal squamous cell carcinoma, a form of head and neck cancer, who may be candidates for therapy de-escalation, such as reduction in radiation therapy intensity.

The AI program successfully identified and stratified patients into low- and high-risk groups by isolating an imaging biomarker from routine digital pathology slides. This analysis revealed HPV-associated cancer patients who may avoid harsher treatments by either receiving lower doses of radiation or foregoing radiation therapy. These findings build upon previous novel imaging biomarker research developed by Case Western's Center for Computational Imaging and Personal Diagnostics.

Ultra-high dose rate "flash" radiotherapy (FLASH-RT)

The National Institutes of Health awarded Penn Medicine researchers a five-year, $12.3 million grant to study an emerging form of radiation therapy treatment that could mean shorter duration and frequency for patients. FLASH-

RT provides ultra-fast doses in under a second, compared to several minutes with conventional radiation. Unlike conventional radiotherapy that requires up to 30 or more treatments, FLASH-RT is designed to be delivered in one to three treatments (Figs. 2, 3). Additionally, when delivered all at once in animal models, FLASH-RT has a sparing effect on some normal tissues without compromising its anti-tumor action.

Figure 2: FLASH radiotherapy delivers ultra-fast doses compared to conventional radiotherapy (ref. 116)

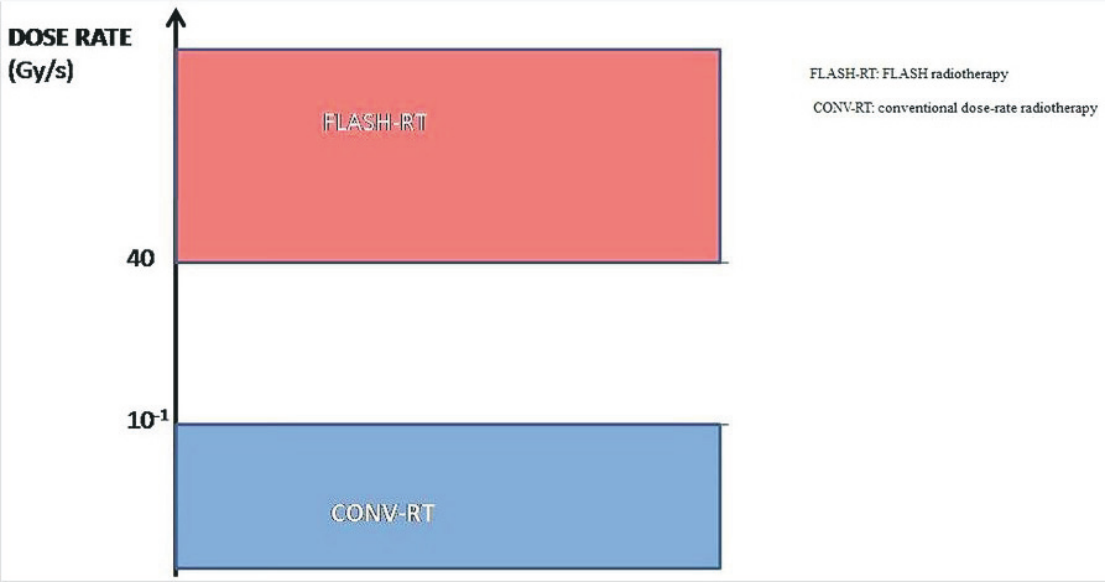


Figure 3: FLASHKNiFE FLASH radiotherapy system (ref. 119)

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About the Contributors

M. Atif Khalid, MD

Senior Medical Director, Radiology, Specialty Health

Dr. Khalid is a U.S. Army Veteran with a career spanning more than twenty years as a board-certified diagnostic radiologist. He has practiced primarily in academic settings, including Hartford Hospital and the University of Connecticut system, large outpatient medical imaging settings, and mid-sized community hospitals. Dr. Khalid's lengthy career has given him the foundation for a thorough understanding of the complexities of the U.S. healthcare system and current standards of care. In his current role, Dr. Khalid is involved in training new physicians, auditing, continuing education, and policy development.

Dr. Khalid has a strong interest in shaping the delivery of healthcare services in our country. His attendance at the Harvard Business Leadership Initiative has further piqued his desire to help transform current payment and delivery systems, as well as the patient experience, beyond the status quo. His experience with the health insurance industry has given him the tools to navigate emerging medical markets, such as Medicaid managed care and Medicare Advantage. His experience managing more than one hundred eighty-five physicians performing utilization management reviews has afforded him the business acumen to be successful in healthcare arenas beyond coverage of services. As the senior medical director for Specialty, Dr. Khalid prides himself on always being available for questions by any physician clinical reviewer, medical doctor's office or health plan clinician. Because of his extensive clinical and corporate leadership experience, Dr. Khalid has helped execute transformative initiatives at Magellan Healthcare.

Dr. Khalid has an ongoing interest in impacting the future of the U.S. healthcare system and is constantly seeking avenues for which he can apply his acquired skills.

William G. Carson, Jr., MD

Medical Director, Hip, Knee and Shoulder Surgery

Dr. Carson, a board-certified orthopedic surgeon, joined Magellan Healthcare in 2015. He oversees the hip, knee and shoulder program and is a member of the Guideline Committee. Throughout his career of more than 30 years, Dr. Carson has been active in orthopedic education and sports medicine and authored numerous articles and textbook chapters pertaining to arthroscopic surgery. He mentors Magellan's orthopedic surgeon reviewers and is active in their training and continuing education. Dr. Carson has also served as a team physician in the National Football League and Major League Baseball. He completed his orthopedic surgery residency at Emory University and a fellowship in sports medicine at the Hughston Clinic.

Susie So Jang, MD

Medical Director, Interventional Pain Management

Dr. Jang, board-certified in anesthesiology and pain medicine, joined Magellan Healthcare in 2019. She provides clinical leadership to Magellan's specialty interventional pain management team and is active in mentoring and training newly hired physicians to ensure quality utilization of pain management interventions. Dr. Jang completed her anesthesia residency and pain medicine fellowship at Beth Israel Deaconess Medical Center in Boston, Massachusetts, where she continued her clinical career of over 10 years as an anesthesiologist and interventional pain medicine physician. During her anesthesia residency and pain medicine fellowship programs, as well as at Harvard Medical School, Dr. Jang was involved in education leadership roles.

Matthew Walker, MD

Medical Director, Spine Surgery

Dr. Walker, a board-certified orthopedic spine surgeon with more than twenty years of clinical experience, joined Magellan Healthcare in 2014. He completed his orthopedic surgery residency at the Summa Health System of Akron, Ohio, and the Orthopaedic Spine Fellowship program of the Mayo Clinic (Rochester, Minnesota). As medical director of spine surgery at Magellan, Dr. Walker is directly involved in creating and implementing spine surgery guidelines and training physicians to ensure high-quality, evidence-based patient care.

Rosalind Watman, DO

Medical Director, Cardiology

Dr. Rosalind Watman is a board-certified cardiologist with over 30 years of experience. She spent most of her clinical career at Nassau University Medical Center in East Meadow, New York, where she was the director of the telemetry unit, director of cardiac ambulatory services, and director of women's health. She also served as the program director for the Osteopathic Internal Medicine and Cardiology Fellowship Programs.

Dr. Watman has worked at Magellan Healthcare since 2014, first as a senior physician reviewer, and currently as the medical director of cardiology, where she is involved in the training of physicians in the appropriate utilization of cardiac studies. In addition, Dr. Watman is involved in creating and implementing cardiac guidelines, as well as collaborating with health plans and providers to provide quality patient care.

Peter Ashline, MD, FACC

Physician Clinical Reviewer, Cardiology

Dr. Ashline, who is board certified in cardiovascular disease, joined Magellan Healthcare in 2019. He is a member of the cardiology leadership team, serves as a mentor to Magellan's cardiology physician reviewers, and participates in their training and continuing education. Prior to joining Magellan, Dr. Ashline was a clinical cardiologist for 22 years. He completed his cardiology fellowship training at the University of Texas.

Amy Crooks, MS, CCC-SLP

Clinical Reviewer, Physical Medicine

Amy Crooks, a certified speech-language pathologist, joined Magellan Healthcare in 2018. Prior to that, Amy was a utilization manager for the specialty therapy division at Centene Corporation. Throughout her career of over 30 years, Amy has gained extensive clinical experience in the field of speech pathology, including all age groups and various patient settings.

At Magellan, Amy is responsible for reviewing health care therapy services to determine consistency with contract requirements, coverage policies, and evidence-based medical necessity criteria. She has worked as a resource on coverage policy guidelines and recently published an article on clinical documentation and the insurance review process in the Leader magazine for the American Speech and Hearing Association.

Jerm Day-Storms, PhD, MWC

Senior Policy Specialist, Medical Policy

Dr. Day-Storms, an experienced certified medical writer and scientist with a demonstrated history of working in the medical policy, research, and higher education industries, joined Magellan Healthcare in June 2021. He earned a Doctor of Philosophy degree in biological chemistry (enzymology) from the University of Michigan Medical School and a Master of Arts degree in biochemistry from Duke University. He is currently the secretary/treasurer of the Florida chapter of the American Medical Writers Association (AMWA).

Noushin Izadifar Hart, MD

Senior Physician Clinical Reviewer, Radiation Oncology

Dr. Hart, a board-certified radiation oncologist, joined Magellan Healthcare in December 2019 as physician clinical reviewer. As senior physician clinical reviewer, since November 2021, she oversees the radiation oncology program. Dr. Hart completed her residency in radiation oncology and a year of research at Washington University. She was a clinical assistant professor at Loyola University School of Medicine in Chicago, Illinois, before moving to Houston, Texas, where she has been in private practice. Combining her nineteen years of clinical experience with eight years of experience in utilization review, Dr. Hart is passionate about evidence-based healthcare delivery.

Mindy Marquez, MD

Physician Clinical Reviewer, Radiology

Dr. Marquez, a board-certified urologist, completed her urology residency at the University of Texas Southwestern Medical Center. In addition to having over 20 years of clinical experience, Dr. Marquez has also served on the editorial board of the Journal of Gynecologic Surgery. She joined Magellan Healthcare in 2019 as a physician clinical reviewer.

Joe Mazzie, DO

Senior Leadership Team Physician Clinical Reviewer, Radiology

Dr. Mazzie, a board-certified radiologist with over 19 years of experience, joined Magellan Healthcare in 2014. He is a graduate of the New York Institute of Technology College of Osteopathic Medicine, where he is currently an associate professor of radiology.

Leigh Stevens, MD, MBA, D.ABA

Physician Clinical Reviewer, Interventional Pain Management

Dr. Stevens is board-certified in anesthesiology and pain medicine. She completed her anesthesia residency at Drexel University/Hahnemann Hospital in Philadelphia, Pennsylvania, and her pain fellowship at the University of Massachusetts/Baystate Medical Center. She joined Magellan Healthcare in a part-time physician clinical reviewer role in 2019. She currently practices interventional pain medicine and anesthesia in North Carolina.

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Glossary

Acronym	Definition
AAC	Augmentative and alternative communication
AI	Artificial intelligence
ARDI	Androgen receptor directed inhibition
ASTRO	American Society for Radiation Oncology
BSoC	Best standard of care
CMS	Centers for Medicare & Medicaid Services
CNB	Cluneal nerve block
CNE	Cluneal nerve entrapment
CPT®	Current Procedural Terminology coding system of the American Medical Association
CRT	Cardiac resynchronization therapy
CT	Computed tomography
CTA	Computed tomography angiography
DOTA	Common name of chelator 1,4,7,10-Tetraazacyclododecane-1,4,7,10-tetraacetic acid
DRG	Diagnosis Related Group
EBRT	External beam radiation therapy
FAP	Fibroblast-activation protein
FAPI	Fibroblast-activation protein inhibitor
FDG	Fluorodeoxyglucose
HF	Heart failure
HPV	Human papillomavirus
ICD	Implantable cardioverter-defibrillator
ICH	Intracranial hemorrhage
IPPS	Inpatient Prospective Payment System
LVO	Large vessel occlusion
mCRPC	Metastatic castrate-resistant prostate cancer
MIPS	Merit-based Incentive Payment System

Acronym	Definition
MPFS	Medicare Physician Fee Schedule
MR	Magnetic resonance
MRI	Magnetic resonance imaging
NIA	National Imaging Associates, Inc.
NTAP	New Technology Add-on Payment
PBS	Pencil-beam scanning
PE	Pulmonary embolism
PET	Positron emission tomography
PNS	Peripheral nerve stimulation
PSMA	Prostate-specific membrane antigen
RCT	Randomized controlled trial
RFA	Radiofrequency ablation
ROI	Region of interest
RT	Radiation therapy
SUV	Standardized uptake value (for imaging studies such as PET and PET/CT)

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