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Dear Dr. Chaguturu,

It has come to our attention that Aetna has published a clinical policy bulletin (Policy #0952, www.aetna.com/cpb/medical/data/900_999/0952.html) on the medical necessity for ultrasound guidance on certain procedures. We have many concerns about the document as outlined below. Indeed, the evidence supporting ultrasound guidance to improve safety, benefits, and in some cases efficacy, is in fact strong. On behalf of our combined membership of >16,000 clinicians, we request a virtual meeting with you within the coming weeks to further discuss the policy. We hope to assist with more effective solutions that will NOT lead to unsafe care, low quality care, or increased barriers to care.

Multiple professional societies are represented by the signers of this letter. Three have led the creation of this response: The American Institute of Ultrasound in Medicine (AIUM), the American Medical Society for Sports Medicine (AMSSM), and the American Academy of Physical Medicine and Rehabilitation (AAPM&R). The American Institute of Ultrasound in Medicine (AIUM, 8,500 members) represents all facets of medical ultrasound, including those who use this imaging technology in the diagnosis and treatment of musculoskeletal and related conditions. The AMSSM (5,036 members) and AAPM&R represent physicians who specialize in diagnosis and treatment of musculoskeletal and neurological conditions, including physically active people and athletes at all ages and skill levels. Multiple other societies share our viewpoints and have endorsed this letter as well.

We have the following specific concerns about the Aetna policy:

- The document fails to consider the significant potential and probable negative effects on **quality of care**, **patient safety**, **access to care**, and **patient satisfaction and confidence**.
- The document fails to consider the **additional costs** that may occur (for multiple reasons) when many of these procedures are not done with ultrasound guidance, which include but are not limited to repeat injections, additional costly diagnostic studies, and (sadly) **serious negative complications**.
- The document is inaccurate in its review of the literature on many key ultrasound guided procedures.
- The document has no known input from leaders or key musculoskeletal societies in the field practicing musculoskeletal ultrasound.
- The document ignores the **community standard of care** for physician practice. For a large percentage of the procedures on the "no proven benefit" list, it would be against the community standard of care to perform the procedure without ultrasound guidance, hence exposing the clinician to medicolegal risk. Indeed, most clinicians wouldn't consider performing many procedures on this list without ultrasound guidance.

Interventional musculoskeletal ultrasound has grown rapidly in the past two decades, both in the US and internationally, as clinicians and healthcare organizations have recognized its cost effectiveness and added value at the point of care. Ultrasound guidance enables many procedures to be done safely and effectively in the office, limiting the need for CT or fluoroscopic guidance with their higher cost, limited patient access, and increased radiation exposure.

The Aetna policy appears to be based on a review of literature that contains large gaps and flaws. Though peer-reviewed literature in this relatively young field remains insufficient in many areas, the body of published research is growing rapidly, and there is abundant clinical evidence supporting many ultrasound-guided musculoskeletal procedures.[1-8] However, the Aetna policy cites many sources that do not review/discuss these topics in adequate depth, and the conclusions or statements being made by Aetna are often not supported by the content from the articles being cited. For example, 11 of 27 different UpToDate articles cited by the policy were simply used to state that "ultrasound guidance was not mentioned in this article" (or similar). This is not grounds to state that ultrasound guidance is not warranted. Furthermore, it is unusual that the Aetna policy so heavily cites UpToDate articles to support its policy. In discussing the issue directly with several UpToDate section editors (from Sports Medicine, Emergency Medicine, Rheumatology, Anesthesiology), all of them favor using ultrasound guidance for injections in their own practice and feel the content of their sections does not support refusal of reimbursement for ultrasound guidance. Also, though all but overlooked by Aetna, UpToDate has published an article which favorably reviews the use of

ultrasound-guidance for musculoskeletal procedures.[8] This peer-reviewed article states, “Ultrasound (US) guidance of the injection and aspiration of joints and related structures improves the accuracy of such procedures and can improve the efficacy and safety of therapeutic injections.”

Below, we list the rationale and literature review which supports the usage of and reimbursement for ultrasound guidance for musculoskeletal procedures. In addition, we highlight key anatomical structures that we feel strongly should not be treated without ultrasound guidance by trained individuals.

Quality of Care

Our most significant objection to this document is the lack of consideration for quality care. Patients deserve to benefit from maximally efficacious and safe interventions. Specifically, withdrawing reimbursement for ultrasound guidance serves as a barrier to high quality care and is not in the patients’ best interest. Case-specific literature that supports this viewpoint is reviewed below.

Safety

Quality care encompasses many aspects, but the most important is safety. Ultrasound guidance decreases risk of harm to the patient during a procedure by allowing direct visualization of critical surrounding structures, reducing the chance of inadvertent injury. Clear identification of nerves and vasculature lying within a proposed needle trajectory is necessary so the physician may recalibrate their approach, to avoid accidental cannulation, laceration, puncture, or inadvertent intravascular injection. Performing many such procedures without image guidance creates serious medicolegal risk.

Inappropriate use of blind injection, as may be encouraged if ultrasound guidance is not reimbursable, may directly harm the patient. In these cases, medical treatment is needed for complications, and there is risk of tort claims. Examples of complications include, but are not limited to: (1) arterial or venous laceration or puncture and resultant hemorrhage and hematoma formation, (2) direct neural damage with both acute and chronic pain and paresthesias, (3) intratendinous injection with delayed tendon rupture, (4) violation of the pleural cavity with pneumothorax, (5) pseudoseptic arthritis or seroma due to injectate being placed outside the intended joint space (e.g., hyaluronic acid injected into Hoffa’s fat pad).

A great many of the cases on Aetna’s “no proven benefit” list must be performed with image guidance for safety reasons. These are discussed in detail in Appendix 1, but two

illustrative examples are included here: the psoas tendon and costochondral joint/intercostal space.

Example 1: Psoas tendon

The psoas tendon lies in intimate association with the femoral nerve, artery, and vein and their many local branches. Use of ultrasound to first identify the surrounding structures is critical to performing a safe and accurate injection procedure, and significant complications are possible. Direct trauma to the femoral nerve may impair ambulation. An inadvertent injection of particulate steroid into an artery/arteriole may lead to embolization and tissue necrosis. Penetration of the femoral vein or artery may cause a large compressive hematoma, requiring advanced imaging for diagnosis and possible hospital admission for management. A psoas tendon injection with anatomic guidance alone is therefore unsafe and poses unnecessary risk. We emphasize that a psoas tendon injection with ultrasound guidance is consistent with standard best practices within the US community of physicians. A physician who performs an injection without ultrasound guidance because it is not reimbursable, despite the community standard of care being to use ultrasound guidance, is apt to be sued and held liable for any harm.

Example 2: Costochondral joint

The costochondral joint is also on “no proven benefit” list, however given the proximity to vital organs, there is risk of serious complications which can easily be prevented by use of continuous ultrasound guidance before, during, and after the procedure. In fact, an NFL quarterback (Tyrod Taylor) is currently suing the LA Chargers’ team physician for a pneumothorax injury sustained due to lack of image guidance being used during intercostal injection procedures. https://theathletic.com/3604891/2022/09/18/giants-tyrod-taylor-lawsuit-chargers/

Lastly, individual patient factors may necessitate ultrasound guidance for safety. An anticoagulated patient is at higher risk of hemorrhage, should a blood vessel be accidentally violated. For such patients with concerning comorbidities, clinicians should utilize ultrasound guidance for safety, and deserve to be reimbursed.

Diagnostic capability of ultrasound at the time of injection

The use of ultrasound during a procedure further enhances quality of care by providing key diagnostic information at the time of injection. This information can affect the type and location of an injection to improve patient outcomes, yet is missed during blind injections. For example ultrasound will allow the physician to determine if joint aspiration

is needed prior to an injection, or if another structure (e.g., loose body, heterotopic ossification, aneurysm, tumor) in proximity may need to be addressed.

Ultrasound guidance provides real-time feedback to the clinician which can be essential in diagnostic planning. For example, rotator cuff and other tendon tears may be missed or over/underestimated by MRI or other diagnostic imaging. Ultrasound-guided injection affords a valuable opportunity to accurately evaluate and quantify/measure the tear. A partial or full-thickness tendon tear will become readily apparent during injection as the tissues lift apart due to fluid flow. It is not uncommon to discover or alter the diagnosis after a guided injection. This can be critical to patient management.

In addition, quality of care is enhanced in the following important ways:

- Limiting the volume of diagnostic steroid injections (potential toxicity)
- Accurate placement of expensive injectates (e.g., botulinum toxin, PRP)
- Reveals any anatomical anomalies/variants which must be accounted for
- Identifies associated pathology which may alter the treatment plan
- Ultrasound guided injections can be better assessed at follow-up than blind injections because the location of needle placement was confirmed and documented. Furthermore, the physician will be able to assess for recurrence of fluid or changes in tissue architecture. This greatly aids clinical decision making.

Patients prefer ultrasound guidance for multiple reasons, which leads to greater patient satisfaction and confidence in the care they have received:

- Reduces patient anxiety and leads to a less painful experience[2,4,7,9]
- Provides enhanced reassurance and education to the patient as they visualize the process in real time.
- It may allow lower volume of injection, as it is more accurate. This is especially critical in patients with difficult anatomy (e.g., obesity).

Cost of care

While quality of care is critical, we recognize the need to control costs in medicine. Appropriate use of musculoskeletal ultrasound and ultrasound-guided injections will decrease the overall cost to the patient and system.[2,3,10] The Aetna policy is likely to lead to increased costs through various mechanisms. It will likely lead to providers ordering more diagnostic testing prior to a blind injection. This would include additional CT and MRI which are far more costly, often lead to additional workup (e.g., chasing “incidentalomas”), reduce healthcare efficiency, and can harm the patient (e.g., delays in treatment, radiation exposure with CT).[11]

In addition, follow up exams after the injection will lack pertinent data and additional advanced imaging may be needed to monitor progress. Furthermore, CT and MRI often do not show the appropriate pathology so the actual injection performed targets the wrong structure and is therefore ineffective.[12] Finally, more patients will likely be referred to outside tertiary care centers or Interventional Radiology for CT- or fluoroscopic guided procedures. Many will not want to take on the risk of blind injections without reimbursement for ultrasound guidance.

The Aetna policy is likely to lead to increased failure rate injections and the need for repeat injections, adding cost or pushing patients into more expensive procedures.[10-13]

4. Lack of discussion with leading medical societies for input

We understand the need for policy decisions by insurance companies to help control expenditures for procedures and to help support adherence to evidence-based medical practices. However, we see no evidence that this policy was reviewed by key stakeholders. Policy such as this can be better informed through dialogue with expert medical societies such as AIUM, AMSSM, AAPM&R, and other organizations, thereby continuing to provide excellent, evidence-based medical care.

In conclusion, patients and physicians will incur increased risk of harms, greater costs, lower satisfaction, and inferior care outcomes if ultrasound guidance is not covered. We look forward to your response and further discussion.

Respectfully,

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ATTACHMENTS:

(1) – Specific inaccuracies in the Aetna Policy
(2) – References

ATTACHMENT 1: Specific Inaccuracies in Aetna Policy

Nerve

In order to accurately identify, localize, and treat diverse types of peripheral nerve entrapment syndromes, use of ultrasound is a powerful diagnostic and interventional tool when standard MRI and/or electrodiagnostics cannot readily pinpoint the problem.[2,14] Once diagnosed, ultrasound is also foundational for treating many peripheral neuropathies. Perineural injections require high precision in order to achieve optimal results and avoid damaging the nerve. Both nerve blocks (in particular diagnostic blocks) and hydrodissection require the physician to target the perineural space, avoiding injection into the nerve itself. The margin of error is within millimeters. Adding to the complexity, nerves are usually located within neurovascular bundles-. Accurate and safe perineural injections cannot be achieved with anatomic guidance alone.

Ultrasound guidance has become the standard of care for anesthesiologists for pre- and post-operative pain control and regional blocks,[15] as well as for interventional pain procedures among orthopedic, sports medicine, rehabilitation, and pain management specialists. The Aetna policy states ultrasound guidance is not supported or reimbursable for many nerve procedures including brachial plexus. This is quite astonishing and requires further discussion. Anterior scalene and brachial plexus blocks (interscalene, subcostal, axillary) are performed either for diagnostic purposes, treating chronic pain, or for regional anesthesia. Before ultrasound guidance became the standard, serious complications such as pneumothorax, hemothorax, and phrenic nerve palsy were common.[15-17] The use of ultrasound guidance has significantly enhanced the safety of these procedures[18] for several reasons: 1) smaller volumes of anesthetic can be used because of more accurate needle placement, 2) anatomic variants of the brachial plexus can be identified in real-time and treated appropriately, 3) visualization of lung helps prevent puncture, leading to pneumo- or hemothorax, and 4) visualization of the vasculature helps prevent accidental puncture or cannulation, which can result in arterial embolism, expanding hematoma, aneurysm, or (if anesthetic is injected into the carotid or vertebral artery) stroke, seizure, or death.[19]

Placing an injectate (commonly a mixture of corticosteroid and local anesthetic) very precisely around a segment of nerve (“hydrodissection” technique) not only decreases inflammation, but also allows the nerve to freely glide from surrounding ligaments, tendons, and vascular structures. This technique is impossible without direct, highly-precise ultrasound guidance, and has been accepted and supported in the literature as a safe and effective method to help treat various nerve disorders.[20-22]

Common entities, including suprascapular or tarsal tunnel neuropathies (e.g. from paralabral or ganglion cyst compression) benefit from use of US guidance and to decrease the risk of aforementioned intraneural or intravascular occlusion/laceration.[22]

Of additional note, the Aetna policy contradicts itself by compensating for ultrasound guidance for carpal tunnel procedures, but not for median neuropathies.

Tendon, Tendon Sheath, and Bursa

Based on systematic reviews, ultrasound guided tendon or tendon sheath injection procedures had a mean accuracy of 87 to 100%, when compared to a mean accuracy of 27 to 60% of traditional landmarked based palpation approaches.[2,7] This distinction becomes even more apparent during the management and treatment of smaller structures such as the wrist (DeQuervain's tenosynovitis, wrist extensor compartment), hand (A1 pulley for trigger finger), or the foot/ankle (peroneal, posterior tibialis, and Achilles paratenon). Without the use of ultrasound guidance to carefully visualize these tendon sheath structures, a clinician cannot assure patients with confidence their needle tip and injected medication will be delivered to the pathologic location and will have an intended positive treatment effect, while minimizing risks (if corticosteroid is used) of musculotendinous injury/rupture, fatty atrophy, or skin depigmentation.

As discussed earlier in the safety and quality of care sections, lack of ultrasound guidance during the treatment and management of common tendon pathologies such as lateral epicondylosis, greater trochanteric pain syndrome, psoas and iliopsoas tendinopathy, adductor, and gluteal tendinopathies will not only increase the chance of sub-optimal therapeutic outcomes, but it will also increase the risk of inadvertent iatrogenic injury to the tendon, adjacent ligament and/or neurovascular bundles. Such complications will lead to consequences of prolonging the treatment course and potentially increasing morbidity by continuing the chronic pain cycle, decreasing function (for example, increased weakness) and overall quality of life, and raising the financial burden of patients due to increased healthcare utilization. Affected patients would often have to be worked up for unnecessary and time-consuming advanced imaging, which may not readily add more diagnostic information when compared to point of care and dynamic musculoskeletal ultrasound and may ultimately lead to preventable and costly surgeries.

Traditional percutaneous needle tenotomy and more advanced procedures such as ultrasonic needle tenotomy (Tenex® or Tenjet®) have been shown to be promising and efficacious for chronic, refractory tendinopathies and cannot be performed safely and accurately without use of real time ultrasound guidance. Structural changes to the tendon, surrounding tendon sheath and fat pad, and associated signs of

neovascularization are conveniently and rapidly performed with US when compared to MRI.

Bursa procedures are more effectively performed when image guidance is used.[23-25] To ask patients to undergo the risk and chance of a subtherapeutic blind palpation injection wastes not only both the patient and physician's time, but may lead to worsening pathology with injectate being placed in an incorrect surrounding structure (for example, for the knee, ligament and exposes articular cartilage to future harm if corticosteroids are used or for retrocalcaneal bursa of the ankle, injecting into Kager's fat pad or into the distal Achilles, leading to fat pad atrophy and risk for delayed Achilles tendon rupture).

Joint

Joint injections are frequently performed in sports medicine and orthopedic practices and the knee joint is the most common. Precision is essential to achieve the best clinical outcome and several studies have provided supporting evidence. Ultrasound guided injections have been shown to be more accurate than landmark guided (US 96% vs. Landmark 81%),[23] led to higher clinical response,[26] higher patient satisfaction,[9] longer time to repeat injections, and reduced patients costs.[27]

Following the knee, the hip joint is frequently injected and due to its proximity to the femoral artery, nerve and vein and depth, accuracy is only achieved with guidance. Ultrasound has been shown to be 97-98% accurate, comparable to fluoroscopic guidance, while also sparing physician and patient exposure to radiation.[4,28] This can also be safely completed in the clinical setting.[6,29] A meta-analysis of 431 injections, confirmed the superiority of ultrasound guided injections over palpation guided.[5]

With regard to the shoulder, the evidence demonstrates that subacromial[25] and glenohumeral injections[1,30] are more precise and cost-effective under ultrasound.[13]

Ligament

Due to its depth within the tissue and inability to discern if the exact location of the needle tip by palpation, visualization is essential for appropriate therapeutic interventions. Ultrasound has been extensively applied to carpal tunnel pathology and has demonstrated to allow successful ligament release safely with less pain and earlier improvement of strength compared to open release.[31]

Fascia

Due to the high prevalence of plantar fasciitis, the plantar fascia is the most commonly injected fascia in the body. Corticosteroid and other injections are often used for refractory cases. Studies have shown that ultrasound improves accuracy of injections

and provides a much lower rate of recurrence (8% vs. 46%) 6 months following injection, which is both statistically and clinically significant.[32] A randomized trial comparing palpation-guided to ultrasound-guided injections did not notice clinical changes between groups due to its short follow-up of 3 months,[33] but may have missed important differences as noted at the 6-month mark in other studies.

ATTACHMENT 2: References

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