Elbow Arthroplasty

Policy
*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers total elbow arthroplasty medically necessary for the treatment of pain unresponsive to medical therapy, when radiographs demonstrate destruction of articular cartilage or gross deformity, inability to use the extremity for functions of daily living because of pain, motion loss, or instability, refractory sepsis, elbow ankylosis after sepsis or trauma and salvage/revision of a failed implant.

Aetna considers arthroplasty with a metal radial head medically necessary in the treatment of an unreconstructible comminuted fracture of the radial head; the clinical literature has shown that silicone implants are not resistant to wear.

Aetna considers the following procedures experimental and investigational because their effectiveness has not been established:

- Total elbow arthroplasty for the treatment of reconstructible comminuted radial head fractures
- Total elbow arthroplasty for the treatment of osteoarthritis secondary to fracture

Policy History

Last Review 10/13/2016
Effective: 08/06/2013
Next Review: 10/12/2017

Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
Elbow hemiarthroplasty for the treatment of humerus fractures

**Background**
Arthroplasty is the surgical reconstruction or replacement of a malformed or degenerated joint that is done to relieve pain and restore range of motion to the joint. Total elbow arthroplasty is indicated for the treatment of pain unresponsive to medical therapy, when radiographs demonstrate destruction of articular cartilage or gross deformity, inability to use the extremity for functions of daily living because of pain, motion loss, or instability, refractory sepsis, elbow ankylosis after sepsis or trauma and salvage/revision of a failed implant.

A fracture of the radial head is a complete or incomplete break in the radius occurring at its head, the disc-shaped portion of the bone closest to the elbow. A comminuted fracture involves the entire radial head, which separates into discrete fragments. This type of fracture involves the head of the radius, the elbow joint, and the soft tissue surrounding the fracture site, including nerves, tendons, ligaments, blood vessels, cartilage, and muscles. The mechanism of injury is usually indirect, resulting from a fall onto the palm of the hand, in which the upper limb is in a variable position of flexion of the elbow, and the forearm in pronosupination. Patients present with pain, swelling, limited motion, especially forearm rotation.

Based on the clinical evidence, arthroplasty with a metal radial head is an acceptable alternative in the treatment of an unreconstructible comminuted fracture. The clinical literature has shown that silicone implants are not resistant to wear.

Burkhart et al (2011) evaluated the objective and subjective outcomes, as well as the radiographic results after elbow hemiarthroplasty (HA) for comminuted distal humerus fractures.
in elderly patients. A total of 10 female patients with a mean age of 75.2 years were treated with elbow HA either for osteoporotic, comminuted distal humerus fractures (n = 8) or for early failed osteosynthesis of distal humerus fractures (n = 2). The mean follow-up period was 12.1 months. All patients were examined and evaluated using the Mayo Elbow Performance Score (MEPS) and the Disabilities of the Arm, Shoulder, and Hand (DASH) score. Radiographic post-operative outcomes were assessed performing antero-posterior and lateral radiographs of the injured elbow. According to the MEPS, 9 patients achieved "good" to "excellent results" and only 1 patient revealed a "fair" clinical outcome. The mean DASH score was 11.5 (range of 0 to 30). The flexion of the affected elbow was 124.5° (range of 95 to 140°), the extension deficit was 17.5° (range of 5 to 30°), the pronation was 80.5° (range of 60 to 90°), and the supination was 79.5° (range of 50 to 90°). The following post-operative complications were seen: 1 triceps weakness, 1 transient ulnar nerve irritation, 1 superficial wound infection, and 2 heterotopic ossifications. None of the patients required explantation of the prosthesis. There was no evidence of loosening, radiolucency, or proximal bone resorption, whereas 1 patient developed progressive osteoarthritis of the proximal ulnar and radial articulation. The authors concluded that elderly patients treated with elbow HA revealed good to excellent short-term clinical outcomes. A high rate of complications occurred but most complications found were minor and re-operation rate was low. These researchers noted that these findings must be regarded as a report on their first experience with HA. As cartilage wear is just a question of time especially in active patients, these investigators cautiously recommended HA only for elderly and multi-morbid low-demand patients. The main drawbacks of this study were its small sample size and short-term follow-up. Its findings need to be validated by well-designed studies.

Argintar et al (2012) stated that total elbow arthroplasty is the current gold standard of treatment for unreconstructable distal humerus fractures; however, longevity of the implant remains a concern in younger, more active patients. Distal humerus HA
offers an alternative and may allow for more durable results. The authors retrospectively evaluated the short-term clinical outcomes of 10 patients who underwent elbow HA for distal humerus fractures. This short-term review suggested that distal humerus HA may be an effective treatment for certain distal humerus fractures. The authors concluded that additional studies must be conducted to further define the role of elbow HA for the treatment of complex fractures of the distal humerus.

Verbeek et al (2012) noted that the optimal surgical management of dislocated 3- and 4-part fractures of the proximal humerus in elderly patients remains unclear. Most used techniques are HA and angle-stable locking compression plate osteosynthesis. In the current literature there is no evidence available presenting superior results between HA and angle-stable locking compression plate osteosynthesis in terms of speed of recovery, pain, patient satisfaction, functional outcome, quality of life or complications. These researchers stated that a randomized controlled multi-center trial will be conducted. Patients older than 60 years of age with a dislocated 3- or 4-part fracture of the proximal humerus as diagnosed by X-rays and CT-scans will be included. Exclusion criteria are a fracture older than 14 days, multiple co-morbidity, multi-trauma, a pathological fracture, previous surgery on the injured shoulder, severely deranged function caused by a previous disease, "head-split" proximal humerus fracture and unwillingness or inability to follow instructions. Participants will be randomized between surgical treatment with HA and angle-stable locking compression plate osteosynthesis. Measurements will take place pre-operatively and 3 months, 6 months, 9 months, 12 months and 24 months post-operatively. Primary outcome measure is speed of recovery of functional capacity of the affected upper limb using the DASH score. Secondary outcome measures are pain, patient satisfaction, shoulder function, quality of life, radiological evaluation and complications. Data will be analyzed on an intention-to-treat basis, using uni-variate and multi-variate analyses. The authors concluded that both HA and angle-stable locking compression
plate osteosynthesis are used in the current treatment of dislocated 3-and 4-part fractures of the proximal humerus. There is a lack of level-1 studies comparing these 2 most-used surgical treatment options. This randomized controlled multi-center trial has been designed to determine which surgical treatment option provides the fastest recovery of functional capacity of the affected upper limb, and will provide better outcomes in pain, satisfaction, shoulder function, quality of life, radiological evaluation and complications.

Hohman et al (2014) reviewed clinical and radiographic results in patients with distal humeral HA. Distal humeral HA with the Latitude prosthesis (Tornier, Saint-Ismier, France) was performed in 8 patients (mean age of 64 years; age range of 33 to 75 years) for unreconstructible fractures of the distal humerus or salvage of failed internal fixation. Clinical outcomes were assessed with the American Shoulder and Elbow Surgeons elbow instrument; MEPS; and DASH questionnaire at a mean of 36 months. Radiologic assessment included radiographs and computed tomography to evaluate olecranon wear and densitometry (dual-energy x-ray absorptiometry). Range of motion, pain, and elbow satisfaction were recorded, and descriptive statistics were used for analysis. A total of 7 patients were available to participate in the follow-up examination. Acute cases (5 patients) scored better than salvage cases (2 patients) on the MEPS (80 points [range of 67 to 95 points] and 65 points [range of 50 to 80 points], respectively) and DASH score (31 points [range of 2.5 to 68 points] and 39 points [range of 17 to 62 points], respectively). The mean arc of elbow flexion and extension was 96° (range of 70° to 130°), with mean flexion of 120° (range of 90° to 135°) and a mean extension loss of 19° (range of 5° to 30°). The mean arc of forearm rotation was 160° (range of 140° to 180°). Re-operation was required in 4 patients because of painful retained hardware; 5 patients reported pain with activities of daily living. The authors concluded that distal humeral HA should be used with caution until such time as longer-term outcome studies are able to show the effectiveness of this procedure.
Sebastia-Forcada et al (2014) noted that there is no consensus on what type of arthroplasty is best for the treatment of complex proximal humeral fractures in elderly patients. In a prospective study, these researchers compared the outcomes of reverse shoulder arthroplasty (RSA) and HA. A total of 62 patients (older than 70 years) were randomized to either RSA (31 patients) or HA (31 patients). One HA patient died at 1 year, and she was excluded. The mean follow-up was 28.5 months (range of 24 to 49). Compared with HA patients, RSA patients had significantly higher (p = 0.001) mean University of California-Los Angeles (29.1 versus 21.1) and Constant (56.1 versus 40.0) scores, forward elevation (120.3° versus 79.8°), and abduction (112.9° versus 78.7°) but no difference in internal rotation (2.7° versus 2.6°; P = .91). The DASH score was higher in the HA patients (17 versus 29; p = 0.001). In the HA group, 56.6 % of tuberosities healed and 30 % resorbed. Patients with failure of tuberosities had significantly worse functional outcomes. There were 2 complications (intra-operative humeral fracture and superficial infection). One patient was manipulated under general anesthesia because of post-operative stiffness. Six patients with HA had proximal migration that required revision to RSA. In the RSA group, 64.5 % of tuberosities healed and 13.2 % resorbed. Functional outcome was irrespective of healing of the tuberosities. Notching was observed in only 1 RSA patient; 1 patient developed a hematoma and another developed a deep infection requiring a 2-stage revision to another RSA. The authors concluded that RSA resulted in better pain and function and lower revision rate. Revision from HA to RSA does not appear to improve outcomes.

Mansat et al (2014) stated that fractures of the distal humerus account for 5 % of osteoporotic fractures in subjects older than 60 years. A history of osteoporosis, co-morbidities, and joint comminution make their management difficult. The therapeutic options are limited to functional treatments, osteosynthesis, or either partial or total arthroplasty. Functional treatment of distal humerus fractures in the elderly subject provides inconsistent results, often with persistence of
pain with a stiff or unstable elbow. Osteosynthesis remains the reference treatment for these fractures, following the principle of stable and rigid osteosynthesis allowing early mobilization. However, joint comminution and a history of osteoporosis occasionally make it impossible to meet this objective, with a considerable rate of complications and surgical revisions. The authors concluded that total elbow arthroplasty remains an alternative to osteosynthesis with very satisfactory immediate results restoring a painless, stable, and functional elbow. These results seem reproducible and sustainable over time. The complication rate is not uncommon with an approximately 10% surgical revision rate. Moreover, elbow HA remains to be validated in this indication.

Giannicola et al (2014) prospectively evaluated preliminary results of the Discovery Elbow System (DES; Biomet, Warsaw, IN) used for acute distal humerus fractures and post-traumatic conditions. These researchers analyzed 24 patients (9 men and 15 women), with a mean age of 69 years (range of 45 to 89). Ten had comminuted distal humerus fractures (group I), and 14 had severe post-traumatic arthritis, chronic instability, or nonunion (group II). Clinical and radiographic evaluations were performed. The pre-operative (group II) and post-operative (both groups) evaluations were assessed with the MEPS and Mayo Elbow Performance Index (MEPI), the Quick Disabilities of the Arm, Shoulder, and Hand score, and the modified American Shoulder and Elbow Surgeons score. Patient satisfaction was evaluated on a 4-point scale. Mean follow-up was 41 months (range of 29-63). At the last evaluation, average flexion, extension, pronation, and supination were 136°, 17°, 80°, and 83°, respectively. The average MEPS, Quick Disabilities of the Arm, Shoulder, and Hand score, and the modified American Shoulder and Elbow Surgeons score were 96, 20, and 84, respectively, and without significant inter-group differences. According to the MEPI, there were 20 excellent, 3 good, and 1 fair result; 20 patients were very satisfied or satisfied with the outcome. A significant increase in the functional scores was observed in group II compared with pre-operative results. Radiological evaluation showed 1 patient with progressive
radiolucency and 1 with a non-progressive radiolucency at the final follow-up. No mechanical failures were observed. Two transient ulnar neuropathies, 1 wound infection, and 1 epicondyle fracture were observed. The authors concluded that the DES yielded promising 2- to 5-year results in the treatment of acute fractures and post-traumatic conditions regarding pain relief, functional improvement, and patient satisfaction, achieving excellent results in most cases. They stated that the DES may represent an effective linked-implant option for total elbow replacement in such patients; however, long-term studies are needed.

Alizadekhkhaiyat et al (2015) noted that total elbow arthroplasty (TEA) is increasingly used for the treatment of advanced elbow conditions to reduce pain and improve function. However, TEA is still associated with a higher complication rate than total hip and knee arthroplasty despite advances in the design and surgical techniques. This prospective clinical study reported the outcome of the DES, which has been in clinical use in the United Kingdom since 2003. The study included a total of 100 Discovery Elbows (April 2003 to January 2010) with a minimum 2-year follow-up, including 75 primary and 25 revisions (60 % women and 40 % men; mean age of 62 years). Outcome was assessed by means of the Liverpool Elbow Score, pain experience, patient satisfaction, range of motion (ROM), and radiographic imaging. The mean follow-up period was 48.5 months (range of 24 to 108). The Liverpool Elbow Score improved from 3.79 to 6.36 (p < 0.001). The percentage of pain-free patients was substantially increased from 7 % pre-operatively to 64 % at the final follow-up. The patient satisfaction rate was over 90 %. The flexion-extension arc and pronation-supination arc increased from 72° to 93° and from 86° to 111°, respectively (p < 0.001). Major post-operative complications included deep infection (2 %), progressive aseptic loosening requiring revision (primary, 5 %; revision 12 %), persistent ulnar neuropathy (3 %), and peri-prosthetic fracture (primary, 6.8 %; revision, 8 %). The authors concluded that the DES resulted in improved function, reduced pain, and high patient satisfaction. Moreover, they stated that long-term
results are needed to evaluate the survivorship of this system.

Heijink et al (2015) noted that treatment of comminuted distal humeral fractures remains challenging. Open reduction-internal fixation remains the preferred treatment, but is not always feasible. In selected cases with non-reconstructable or highly comminuted fractures, total elbow arthroplasty has been used, however, also with relatively high complication and failure rates. Distal humerus prosthetic hemiarthroplasty (DHA) may be an alternative in these cases. These investigators reported the mid-term results of 6 patients who were treated by DHA for acute and salvage treatment of non-reconstructable fractures of the distal humerus. All 6 patients were treated by DHA for acute and salvage treatment of non-reconstructable fractures of the distal humerus. Medical records were reviewed, and each patient was seen in the office. Mean follow-up was 54 months (range of 21 to 76). Implant survival was 100%; 3 were pain-free and 3 had mild or moderate residual pain. Average flexion-extension arc was 95.8° (range of 70° to 115°) and average pronation-supination arc was 165° (range of 150° to 180°). In 3, there was some degree of instability, which was symptomatic in 1. One had motoric and sensory sequelae of a partially recovered traumatic ulnar nerve lesion. According to the MEPS, there were 3 excellent, 1 good and 2 poor results; 4 were satisfied with the final result, and 2 were not. The authors concluded that in this case series of 6 patients with DHA for non-reconstructable distal humerus fractures, favorable mid-term follow-up results were seen; however, complications were also observed.

Hemiarthroplasty for Distal Humeral Fractures:

Nestorson et al (2015) reported their experience of performing an elbow hemiarthroplasty in the treatment of comminuted distal humeral fractures in the elderly patients. A cohort of 42 patients (3 men and 39 women, mean age of 72 years; range of 56 to 84) were reviewed at a mean of 34.3 months (range of 24 to 61) after surgery. Functional outcome was measured with the MEPS and ROM; DASH was used as a patient rated
evaluation. Complications and ulnar nerve function were recorded. Plain radiographs were obtained to assess prosthetic loosening, olecranon wear and heterotopic bone formation. The mean extension deficit was 23.5° (range of 0° to 60°) and mean flexion was 126.8° (range of 90° to 145°) giving a mean arc of 105.5° (range of 60° to 145°). The mean MEPS was 90 (range of 50 to 100) and a mean DASH score of 20 (range of 0 to 63); 4 patients had additional surgery for limited ROM and 1 for partial instability. One elbow was revised due to loosening, 2 patients had sensory ulnar nerve symptoms, and radiographic signs of mild olecranon wear was noted in 5 patients. The authors concluded that elbow hemiarthroplasty for comminuted intra-articular distal humeral fractures produced reliable medium-term results with functional outcome and complication rates, comparable with open reduction and internal fixation and TEA. The main drawbacks of this study were its relatively small sample size (n = 42) and mid-term follow-up (34.3 months).

Comminuted Radial Head Fractures:

In a retrospective study, Moghaddam and colleagues (2016) examined how well the modular metallic radial head implant EVOLVE prosthesis restores functional ROM and stability of the elbow in acute care. A total of 85 patients with comminuted radial head fractures and associated injuries received treatment with an EVOLVE prosthesis between May 2001 and November 2009; 75 patients were available for follow-up. On average, patients were followed for 41.5 months (median of 33.0; 4.0 to 93.0). Outcome assessment was done on the basis of pain, ROM, strength, radiographic findings, and functional rating scores such as Broberg and Morrey, the MEPI, and DASH. Overall, there were 2 (2.7 %) Mason II fractures, 21 (28 %) Mason III fractures, and 52 (69.3 %) Mason IV fractures. Arbeitsgemeinschaft fur osteosynthesefragen (AO) classification was also determined. Average scores for the cohort were as follows: Morrey, 85.7 (median of 90.2; range of 44.4 to 100); MEPI, 83.3 (85.0; 40.0 to 100); and DASH 26.1 points (22.5; 0.0 to 75.8). Mean flexion/extension in the
affected joint was 125.7°/16.5°/0° in comparison to the non-injured side 138.5°/0°/1.2°. Mean pronation/supination was 70.5°/0°/67.1° in comparison to the non-injured side 83.6°/0°/84.3°. Handgrip strength of the injured compared to the non-injured arm was 78.8%. The following complications were also documented: 58 patients had peri-prosthetic radiolucency shown to be neither clinically significant nor relevant according to evaluated scores; 26 patients had moderate or severe peri-articular ossification, and scored substantially worse according to MEPI and Morrey. Four patients required revisional surgery due to loosening of the prosthesis and chronic pain. In addition, 1 patient required a neurolysis of the ulnar nerve, 1 developed a neobursa, and 1 had extensive swelling and blistering. The time interval between injury and treatment appeared to have an effect on results; 35 patients were treated within the first 5 days after accident and showed better results than the 40 patients who were treated after 5 days. The authors concluded that comminuted radial head fractures with elbow instability can be treated well with a modular radial head prosthesis, which restored stability in acute treatment. They stated that the modular radial head arthroplasty used in this study showed promising findings in short to mid-term results.

Furthermore, the American Academy of Orthopaedic Surgeons’ guideline and evidence report on “The treatment of distal radius fractures” (AAOS, 2009) did not mention elbow arthroplasty as a therapeutic option.

Osteoarthritis Secondary to Fracture:

Celli (2016) stated that during the past decade, TEA procedures have increased because of an increase in the number of trauma patients. Even though most current posterior approaches to the elbow provide excellent joint exposure, they involve the risk of extensor mechanism injury and of eventual insufficiency, particularly in patients with osteoarthritis (OA) secondary to fracture. The author described a new triceps exposure approach for TEA, the anconeus-triceps lateral flap, which has
proved valuable in patients with distal humeral and olecranon fracture malunion, and its preliminary results at a minimum follow-up of 24 months. A total of 20 consecutive patients with OA due to distal humeral and olecranon fracture malunion underwent TEA by the anconeus-triceps lateral flap approach, which preserves the olecranon insertion of the medial portion of the triceps proper tendon. At a mean follow-up of 33 months, the mean MEPI rose from 41.3 to 94.3. The mean pain score on the visual analog scale (VAS) fell from 7.1 to 1.1. There were no patients with insufficiency, secondary detachment of the triceps tendon, or grade 4 to 5 of the Medical Research Council (MRC) scale. The author concluded that these preliminary data suggested that preservation of the insertion of the medial portion of the triceps proper tendon enabled earlier active rehabilitation. Moreover, the new approach provided optimum exposure of the olecranon also in patients with OA secondary to intra-articular fracture of the distal humerus and olecranon, where scarring and bone deformity usually hamper joint exposure.

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<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-9 Codes</th>
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<tr>
<td><strong>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;+&quot;:</strong></td>
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</table>

**ICD-10 codes will become effective as of October 1, 2015:**

**CPT codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>24360</td>
<td>Arthroplasty, elbow; with membrane (eg, fascial)</td>
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<tr>
<td>24361</td>
<td>with distal humeral prosthetic replacement</td>
</tr>
<tr>
<td>24362</td>
<td>with implant and fascia lata ligament reconstruction</td>
</tr>
<tr>
<td>24363</td>
<td>with distal humerus and proximal ulnar prosthetic replacement (eg, total elbow)</td>
</tr>
<tr>
<td>24365</td>
<td>Arthroplasty, radial head</td>
</tr>
<tr>
<td>24366</td>
<td>with implant</td>
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<tr>
<td>Code</td>
<td>Description</td>
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<td>----------------------------------------------------------------------------</td>
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<tr>
<td>M00.021 - M00.029</td>
<td>Pyogenic [septic] arthritis [elbow]</td>
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<td>M00.121 - M00.129</td>
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<td>M00.221 - M00.229</td>
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<td>M00.821 - M00.829</td>
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<tr>
<td>M00.9</td>
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<tr>
<td>M24.621 - M24.629</td>
<td>Ankylosis, elbow</td>
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<tr>
<td>M25.321 - M25.329</td>
<td>Other instability, elbow</td>
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<tr>
<td>M25.521 - M25.529</td>
<td>Pain in elbow</td>
</tr>
<tr>
<td>S52.121+ - S52.126+</td>
<td>Fracture of head of radius</td>
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<tr>
<td>T84.410+ - T84.498+</td>
<td>Mechanical complication of other internal orthopedic devices, implants and grafts, initial encounter [elbow]</td>
</tr>
<tr>
<td>T84.50x+, T84.559+</td>
<td>Infection and inflammatory reaction due to internal joint prosthesis [elbow]</td>
</tr>
<tr>
<td>S42.401+ - S42.496+, S49.101+ - S49.199+</td>
<td>Fracture of lower end of humerus</td>
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</table>

**ICD-10 codes covered if selection criteria are met:**

- M00.021 - M00.029: Pyogenic [septic] arthritis [elbow]
- M00.121 - M00.129
- M00.221 - M00.229
- M00.821 - M00.829
- M00.9
- M25.321 - M25.329: Other instability, elbow
- M25.521 - M25.529: Pain in elbow
- S52.121+ - S52.126+: Fracture of head of radius
- T84.410+ - T84.498+: Mechanical complication of other internal orthopedic devices, implants and grafts, initial encounter [elbow]
- T84.50x+, T84.559+: Infection and inflammatory reaction due to internal joint prosthesis [elbow]

**ICD-10 codes not covered for indications listed in the CPB:**

- S42.401+ - S42.496+, S49.101+ - S49.199+: Fracture of lower end of humerus
The above policy is based on the following references:


22. Mansat P, Bonnevialle N, Rongieres M, et al. The role of


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AETNA BETTER HEALTH® OF PENNSYLVANIA

Amendment to
Aetna Clinical Policy Bulletin Number: 0857
Elbow Arthroplasty

There are no amendments for Medicaid.

www.aetnabetterhealth.com/pennsylvania
Revised 04/2017