Clinical Policy Bulletin: Elbow Arthroplasty

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Policy

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 elbow hemiarthoplasty experimental and investigational for the treatment of humerus fractures because the effectiveness of this approach has not been established.

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 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 Mayo Elbow Performance Score, 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; Mayo Elbow Performance Index; 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 Mayo Elbow Performance Score (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.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:
ICD-9 codes covered if selection criteria are met:

- 711.02  Pyogenic [septic] arthritis [elbow]
- 718.52  Ankylosis of joint [elbow]
- 718.82  Other joint derangement, not elsewhere classified [instability of elbow joint]
- 719.42  Pain in joint [elbow]
- 813.05  Fracture radial head
- 996.40 -  Mechanical complication of internal orthopedic device, implant
- 996.49  and graft
- 996.66  Infection due to internal joint prosthesis

The above policy is based on the following references:
