

BESS Surgical Procedure Guidelines (SPGs).

Optimising Surgical Outcomes for Shoulder and Elbow patients.

The British Elbow and Shoulder Society (BESS) SPGs are a series of evidence and consensus **Best Practice Recommendations** developed by BESS surgeons and physiotherapists to help drive quality improvement and achieve the best possible surgical outcomes for UK patients. This SPG on primary and revision elbow replacement surgery is supported and endorsed by both the British Orthopaedic Association (BOA) and the Getting It Right First Time (GIRFT) Programme.

The Provision of Primary and Revision Elbow Replacement Surgery in the NHS

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1. Introduction

Total elbow replacement (TER) is used in the treatment of inflammatory arthritis (particularly adult rheumatoid and juvenile idiopathic arthritis), osteoarthritis and post traumatic arthritis as well as in the primary treatment of some complex distal humeral fractures.

Whilst the commonest indication for TER has been adult rheumatoid arthritis, the number of these patients requiring TER has decreased with the use of disease modifying anti rheumatic drugs (DMARDS). This has led to a significant reduction in the number of replacements done both at the surgeon and unit level for inflammatory arthritis. However, the use of total elbow arthroplasty in the treatment of fractures of the distal humerus has become somewhat more common. More recently, distal humeral replacement (Elbow Hemiarthroplasty) for the treatment of unfixable acute distal humeral fractures is being used in selected elderly patients. Despite these changes of indication in the use of TER and Elbow Hemiarthroplasty, the national numbers of patients requiring this type of surgery remains low.

In 2015 the GIRFT report sought to rationalise the delivery of Orthopaedic care within the National Health Service in England, addressing both cost and efficiency¹. One aspect of surgical provision that faced criticism was that of “low volume” procedures such as TER. It is for this reason that BESS has been asked by the GIRFT programme to provide guidelines and recommendations for the provision of primary and revision TER.

The valuable role of TER to improve patient pain and function in appropriate patients cannot be underestimated and remains a very important part of the surgical treatment of elbow pathology. BESS supports the delivery of this surgery in the most effective and safe way for patients. It is for this reason, in response to the changes in the use of TER and the important requirement for rationalisation of this low volume procedure that BESS have prepared this SPG. It has been developed and approved by representatives of BESS through a working group and a consultation process, to produce both consensus and evidence based recommendations.

1.1 Shared decision making and continuity of care

When managing patients who are being considered for primary and revision elbow replacement surgery, the core principles of both shared decision making and continuity of care still need to be discussed and adhered to.

The General Medical Council's 'Good Medical Practice – duties of a doctor' guide² clearly states in the section on working in partnership with patients that doctors should:

- Listen to patients and respond to their concerns and preferences
- Give patients the information they want or need in a way they can understand
- Respect patients' right to reach decisions with the doctor about their treatment and care
- Support patients in caring for themselves to improve and maintain their health

This can only be achieved by direct consultation between the patient and their treating clinician. Decisions about treatment taken without such direct consultation between patient and treating clinician are not appropriate, as they do not adhere to principles of good medical practice.

Continuity and co-ordination of care are also essential parts of the General Medical Council's Good Medical Practice guidance². Therefore it is inappropriate for a clinician to treat a patient if there is no clear commitment from that clinician, the healthcare provider or the commissioners to oversee and fund the complete care pathway of that patient including their diagnosis, treatment, follow-up and adverse event management.

2. Current status of Primary and Revision total elbow replacement surgery

The UK National Joint Registry (NJR) has been collating data for TER since 2012 and now publishes the total number of replacements registered annually as well as providing a

regional breakdown of cases done (Table1) ³. During 2013 the number of total elbow replacements performed was 407 and in 2016, it was very similar, at 401³. While there has been little change over this time period, the NJR report highlights a trend towards a greater proportion being performed for trauma. However, these numbers still remain very low when compared to total hip replacement for which the same document records a total of 101,651 during 2016. Closer analysis of the elbow data identifies that the number of centres providing elbow replacement in 2016 was 141, averaging only 2 or 3 procedures in each centre. Indeed, the number of consultants performing total elbow replacement was 170, averaging only 2 or 3 procedures by each surgeon³. More significantly 73 surgeons performed only 1 TER in 2016³. Further, review of the UK NJR data for 2016 shows that the number of revision elbow replacements recorded was only 55³.

There is considerable evidence within the orthopaedic literature that higher volumes of surgical procedures in lower limb arthroplasty^{4,5,6} lead to better patient results, as assessed by dislocation, revision, infection and mortality rates. The evidence concerning volume of procedures specifically for elbow arthroplasty is very limited but review of both the Finnish and Scottish Arthroplasty registers^{7,8} and from a study in New York State⁹ indicates that the survivorship of total elbow arthroplasty is improved in higher volume surgeons. It has also been reported by the same groups (and others) that meaningful outcome data cannot be obtained for surgeons and hospitals purely based on the operative experience of 1-2 TERs annually ^{8,10,11}. Therefore the issue of case-volume raised by GIRFT is a valid and important point which BESS supports and seeks to address in this SPG.

3. Future provision of Primary and Revision Total Elbow Replacement Surgery

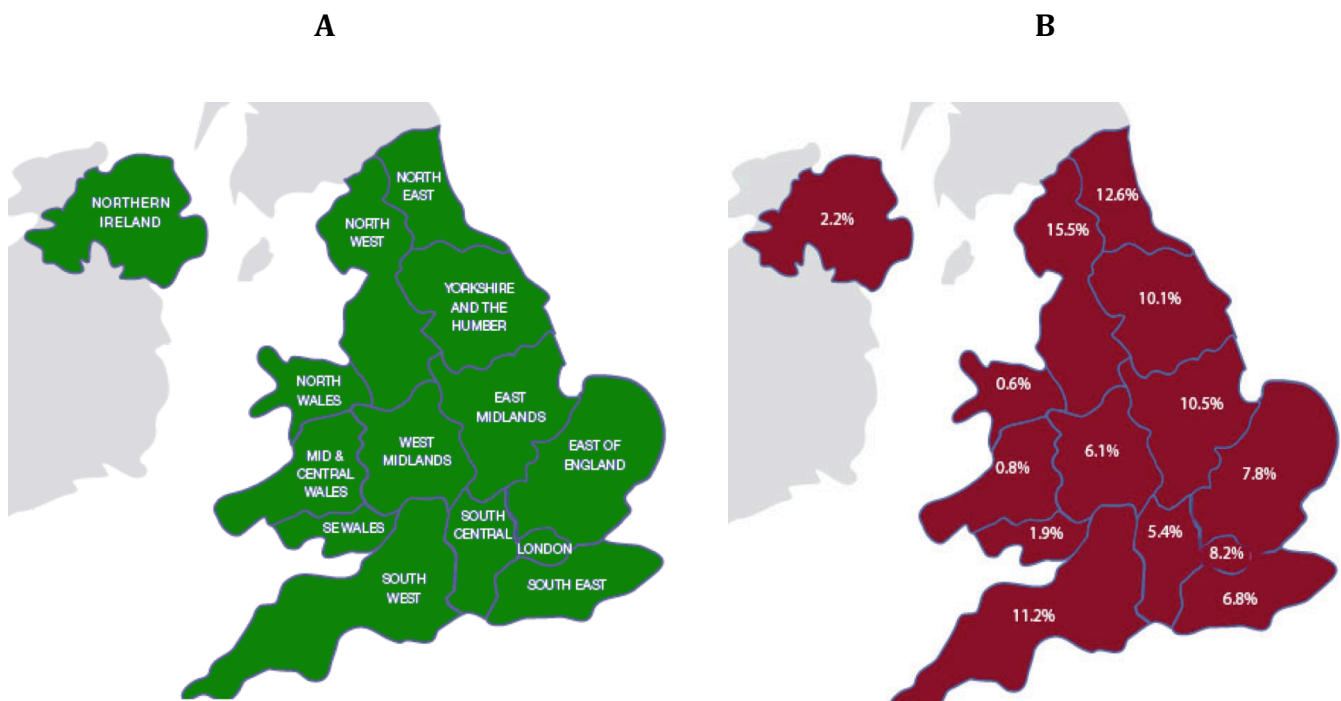
In view of the issues associated with low volume surgery mentioned in the section above and given the potentially complex nature of elbow replacement surgery compared to other joint replacement whilst also taking in to account the justifiably increased scrutiny at centre and surgeon level, there is now a sensible argument to reduce the number of providers. In turn this will increase the average number of procedures performed in regional centres and further concentrate both experience and expertise. Inevitably this will enhance the competence of surgeons and improve overall patient outcome. There will also be the additional benefit of helping to nurture innovation and newer techniques as more national experts emerge driving quality improvement and producing more meaningful outcome data for audit and research on this subject. The centralisation of specialist practice to defined

centres is not a new concept and is established in Neurosurgery, Plastic Surgery, Cardiothoracic Surgery and more recently in orthopaedics with Trauma networks.

Complex revision TER already tends to be undertaken in a smaller number of centres usually regional centres where specialised resources are available. As such the centralisation of primary TER to these same centres makes much sense. Such an organised referral network for TER would ensure that these surgical procedures are undertaken in hospitals with adequate surgical resources and experience. This would further drive improvements in governance, teaching and training, as well as improving evidenced based patient selection for TER.

Many surgeons and Trusts within the UK regions have already begun organising their regional TER network with regional centre and referring hospitals. Within such proposed networks, and given the potential geographical and demographic differences between the centres and their peripheral units it is likely that a pragmatic approach encompassing a measure of flexibility will be necessary in implementing change. However, the central premise to avoid low volume surgery should be adhered to in order to comply with the GIRFT programme principals that are endorsed by NHS Improvement.

Figure 1: Green map (A) highlights regions by old strategic health authority. Red map (B) highlights the percentage of all elbow replacement procedures within region compared to the annual national number in 2016/17.



3.1 Service provision requirements for Primary and Revision Elbow Replacement Surgery

The GIRFT Programme expects positive changes to the provision of TER surgery in the UK. BESS strongly recommends to its membership they make the following changes to the structure of TER provision. The Regional Centres that will provide this service should fulfil these criteria in order to enable TER procedures to be performed as safely and as effectively as possible and to drive further quality improvement.

- It is generally expected that the surgeons and units that have been regularly undertaking revision TER will also be the future centres undertaking primary TER.
- In keeping with a “hub and spoke” model of referral (see figure 2), within each perceived region or “network” there will generally be one or two centres which will be regarded as the Regional Centre/s. This will most likely be the established centre or centres that already deal with primary and revision arthroplasty. This may be a teaching centre or indeed a district hospital but its status is defined by the expertise and resource it offers.
- Within each region, BESS surgeons from the peripheral units and the regional centres should have flexibility to decide on sensible patient referral processes and post-operative follow up pathways.
- In the case of very large geographical regions encompassing a number of Deaneries an argument for a third Regional Centre might be justified based on patient demographics, road and rail links and service demand for TER. BESS surgeons within such a region will need to discuss, agree and plan the need for any 3rd Centre.
- If a region has too many proposed Regional Centres which would unduly dilute case numbers, then BESS surgeons within the region should have the initial opportunity to discuss and agree the selection of the Regional Centres through their TER network and their knowledge of referral numbers and patterns. If uncertainty continues, then the GIRFT programme plan to inform the decision based on previous NJR numbers and unit resources in order to resolve the choice of Regional Centre.
- It would be expected that in the larger regions with 2 or 3 Centres, that the regional network might decide and mutually agree that one hub in particular deals with the more complex multiple revision cases.
- Consultants from a peripheral unit who might wish to continue to be involved in elbow replacement surgery should be encouraged to arrange honorary contracts in the Regional Centre. In turn the Regional Centre NHS Trust management should facilitate this process so that consultants from the peripheral unit can assist with or perform TER in the Regional Centre.

- Jointly performed procedures by two consultants should be considered for complex primary and revision elbow replacements in the centre. There should be a clear mechanism guided by the National Joint Registry to attribute the procedure to both consultants.
- The centre should also provide elbow replacement for trauma. This may be either TER or in selected cases Elbow Hemiarthroplasty as decided by the treating surgical team. As this operation is not an emergency procedure, patients can usually travel for surgery from peripheral units. Any delays for 2-3 weeks will allow the soft tissue envelope to settle and many surgeons feel this is likely to be more advantageous than adversely affecting outcome following TER for acute trauma. The best referral pathway should be decided by BESS surgeons within the regional network. It is anticipated that on some occasions travel will be impractical and refused and the procedure may have to be undertaken at the peripheral unit. Under this rare circumstance, it would be expected that the peripheral unit surgeons who perform this surgery are those same surgeons who have been attending and involved in elbow replacement surgery in the Regional Centre.
- The centres should facilitate and provide training for consultants and orthopaedic trainees wishing to gain more experience in elbow replacement surgery. Specialist “Elbow Fellowships” need to be provided to produce the next generation of elbow surgeons.
- The centre must be fully resourced with all appropriate staff and all equipment routinely available in theatres for primary and revision elbow replacement surgery.
- The centre will need appropriate microbiology services, ideally with meetings of the Multi-Disciplinary Team to plan management of elbow peri-prosthetic joint infections. (see BESS Guidelines on Prosthetic Joint Infection)
- The centre should have a vascular service within reasonable access should a vascular emergency arise.
- The centre, which will also manage revision cases, should have access to a plastic surgery service to help with soft tissue cover e.g. in infected complex revision cases.
- An appropriate specialist rehabilitation service should be made available to patients undergoing this procedure. This may then be undertaken closer to home if necessary but this should be left to the individual networks to organise and regional variation due to geography would be expected.
- Outcome metrics are critical and all cases must be recorded in the NJR including relevant PROMS. Each regional centre is also encouraged to audit its own results

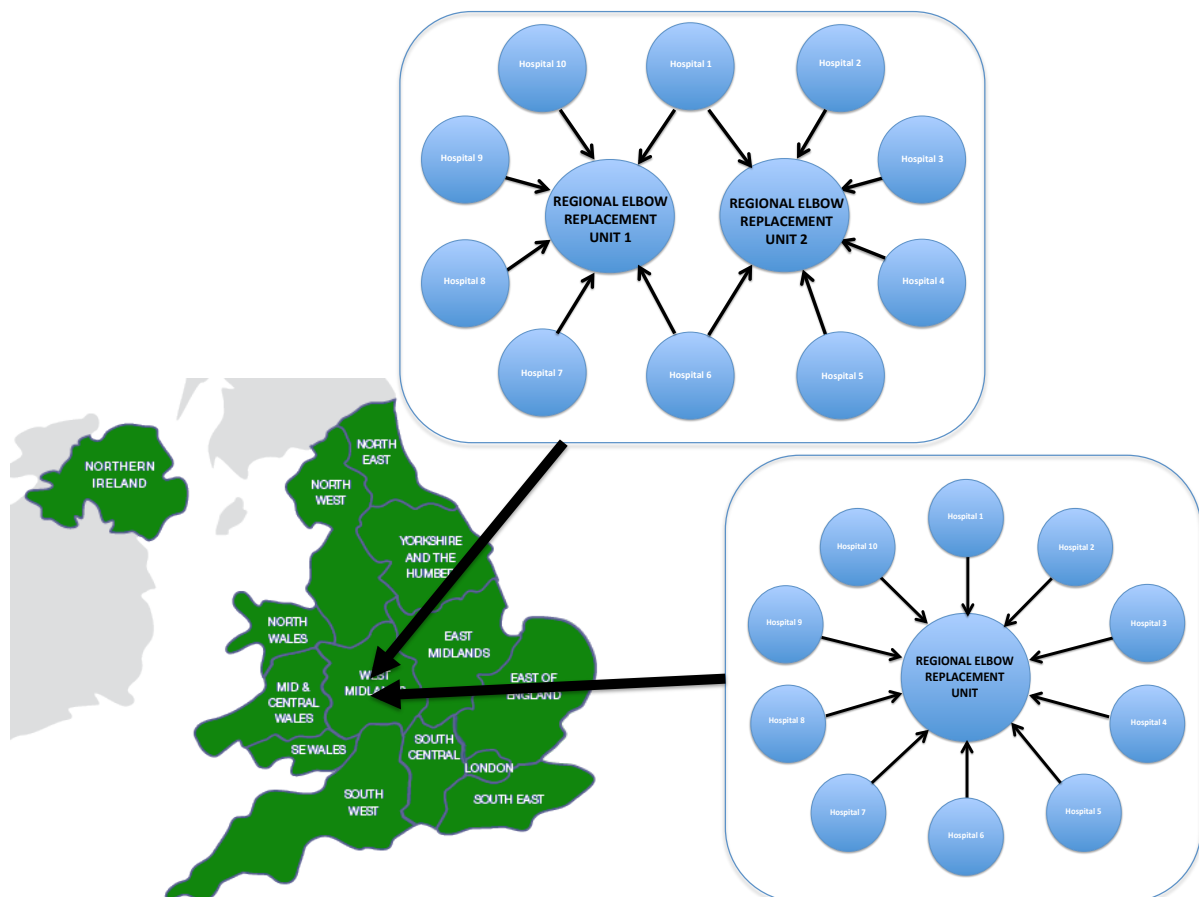
annually by recording its own outcome data locally. Patients will need annual follow up with PROMS and serial x-rays.

- Overburdening a unit with this work may unduly restrict a surgeons practice and experience. Appropriate consultant business cases based on service demand should therefore be supported.
- It is also recommended that this tertiary referral hub and spoke model should not be part of the 18 week pathway. This is particularly pertinent in relation to complex elbow revision surgery where further investigations and a multi disciplinary team input is needed. This is to ensure that Trusts who become the regional centres are not unduly penalised for offering such a service

3.2 Regional Structure – Hub and Spoke Model

Based on service demands and provision of services highlighted in Figure 1 some regions will have one central hub whilst 2 hubs may be needed in other regions. Figure 2 shows examples of both a single and double hub and spoke referral and treatment models.

Figure 2. Example of both a single and double regional hub and spoke model



3.2. Rehabilitation – central versus local

Regional centres performing TER should have the resources to provide specialist physiotherapy services, where dedicated named staff have experience of treating patients following this type of surgery. Physiotherapy may be undertaken closer to home if necessary but this should be left to the individual networks to organise. However, the regional centre physiotherapy service (“hub”) should act as a reference point for all physiotherapists in the wider network, and should provide post-operative rehabilitation guidelines (see BESS website) for every patient whose care is transferred, as well as on going advice, support and training as required to the “spoke” hospital physiotherapist.

Ideally individual networks would have named therapists at each “hub” site, who act as a physiotherapy liaison. Their role would be to facilitate transfer and to support the physiotherapists treating the patients closer to home to ensure the best possible advice and post operative rehabilitation is given to these patients.

3.3 Outcome Metrics

The following outcome metrics should be routinely recorded by any centre performing primary or revision elbow replacement surgery. Contributing data and cases to the National Joint Registry (NJR) is mandatory.

- Length of stay
- Re-admission rate within 30 days
- Mortality rates
- PROM pre-procedure, and minimum 6 months post procedure
- Infection / other adverse events
- Revision rates

Each regional centre should also audit its own results annually by recording its own outcome data locally. While the literature is limited, variable outcomes and survival has been observed. It is therefore recommended that patients will ideally need annual follow up with PROMS and serial x-rays to identify any problems with loosening and associated bone loss.

4. Coding and Finance

Appropriate diagnostic and procedural coding of procedures is vital for correct HRG mapping and for accurate data collection. For best practice in coding it is important for clinicians to engage with trained coders to ensure that all clinical coding standards are followed. It is also

critical that all complications and comorbidities (CCs) are recorded. The current HRG4+ system is very granular and payment is dependent on the number of CCs.

The most common diagnostic and procedural codes for elbow replacement are listed in the **coding appendix 1**. Also listed are the base HRGs that the procedures map to. The precise HRG will be determined by a number of factors including the number of complications and comorbidities.

Appropriate remuneration of actual costs for this specialist service provision is critical. Such service reconfiguration must not be delivered at negative cost to the centre and funds will need to follow service delivery. With an increasing workload, it is important that adequate and appropriate funding is provided to the centre in order to cover the additional resource costs for staffing, training, theatre and ward costs, equipment and rehabilitation.

The current 17/18 and 18/19 national tariff is not able to provide the extra funding required for this service change. The earliest that a new tariff mechanism can be created will be for the year 19/20 and these discussions are underway. If this new model of provision of TER is introduced prior to 19/20 then an interim tariff funding mechanism would be needed.

5. Research and Audit

- Patient Reported Outcome Measures - A validated clinical score, preferably a patient reported outcome measure (PROM), should be used preoperatively and following treatment.
- Acceptable scores include Disability of Arm, Shoulder and Hand [DASH], and the Oxford Elbow Score (OES). Other measures like EQ5D may be used for assessment of general well-being and economic analysis
- Scores should be captured preoperatively and minimum six months following intervention, which allows longitudinal analysis to determine magnitude of treatment effect and consequences of any treatment related adverse events.
- Arthroplasty or replacement procedures should be entered onto the National Joint Registry (NJR) in order to monitor outcomes, complications and longer-term survivorship of implanted prostheses.

6. Patient/Public/Clinician Information

- Referring centres to provide patient information on TER and to include and explanation of why patients will need to travel to a regional centre.

- BESS Information document (in production)
- Regional centres to provide patient information on risks and benefits of TER including revision rates.
- Clinician information
 - Ensure access to NJR reports and regional audit data.
 - BESS Rehabilitation Information after TER

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Coding Appendix 1: Diagnostic and procedure codes and HRG mapping

ICD 10 DIAGNOSTIC CODES

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ICD-10 codes, terms and text used by permission of WHO, from: International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10). Vols 1-3. Geneva, World Health Organization, 1992-2016

Osteoarthritis of elbow

M19.0 Primary arthrosis of other joints

M19.1 Post-traumatic arthrosis of other joints

M19.2 Other secondary arthrosis

Rheumatoid arthritis of the elbow

M05 Seropositive rheumatoid arthritis

M06.0 Seronegative rheumatoid arthritis

M06.1 Adult-onset Still disease

M06.4 Inflammatory polyarthropathy

M08.0 Juvenile rheumatoid arthritis

For the ICD codes above a site code needs to be added as a fifth character. For the elbow the site code is .2 - Upper arm includes humerus and elbow.

Distal humeral fracture

S42.40 Fracture of lower end of humerus – closed

S42.41 Fracture of lower end of humerus – Open

M84.02 Malunion of fracture

M84.12 Nonunion of fracture

M84.22 Delayed union of fracture

Periprosthetic fracture (without an identified cause)

M96.6 Fracture of bone following insertion of orthopaedic implant, joint prosthesis, or bone plate

Periprosthetic fracture (with a traumatic cause)

M96.6 Fracture of bone following insertion of orthopaedic implant, joint

Prosthesis or bone plate

Plus the relevant code for type of trauma from Chapter XX - External causes of morbidity and mortality (Trust hospital coders should help with this)

Intraoperative fractures (including intraoperative periprosthetic/peri-implant fractures)

A code from Chapter XIX Injury, poisoning and certain other consequences of external causes (S00-T98) that classifies the fractured bone

Y79.2 Orthopaedic devices associated with adverse incidents, prosthetic and other implants, materials and accessory devices

Example S72.30 Fracture of shaft of femur

Y79.2 Orthopaedic devices associated with adverse incidents, prosthetic and other implants, materials and accessory devices

Aseptic loosening

T84.0 Mechanical complication of internal joint prosthesis

This includes breakdown (mechanical), displacement, malposition, obstruction, perforation, protrusion etc

Infection

T84.5 Infection and inflammatory reaction due to internal joint prosthesis

Pathological fracture

M90.72A Fracture of bone in neoplastic disease (C00-D48D) – HD39H

OPCS 4 PROCEDURE CODES

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Total elbow replacement

O21 Total prosthetic replacement of elbow joint using cement

- O21.1 Primary total prosthetic replacement of elbow joint using cement
- O21.2 Conversion to total prosthetic replacement of elbow joint using cement
- O21.3 Revision of total prosthetic replacement of elbow joint using cement
- O21.4 Revision of one component of total prosthetic replacement of elbow joint using cement

O22 Total prosthetic replacement of elbow joint not using cement

- O22.1 Primary total prosthetic replacement of elbow joint not using cement
- O22.2 Conversion to total prosthetic replacement of elbow joint not using cement
- O22.3 Revision of total prosthetic replacement of elbow joint not using cement
- O22.4 Revision of one component of total prosthetic replacement of elbow joint not using cement

Lateral resurfacing replacement

- W58.1 Primary resurfacing arthroplasty of joint
- Z81.5 Elbow joint

Elbow hemiarthroplasty

- W52.1 Primary prosthetic replacement of articulation of bone using cement NEC
- W53.1 Primary prosthetic replacement of articulation of bone not using cement NEC
- W53.3 Revision of prosthetic replacement of articulation of bone not using cement NEC
- Z69.7 Lower end of humerus NEC

Change of polyethylene inserts

- O23.4 Attention to total prosthetic replacement of elbow joint NEC
- Y03.6 Adjustment to prosthesis in organ NOC

ORIF for peri prosthetic fracture

- W20.1 Primary open reduction of fracture of long bone and extramedullary fixation using plate NEC
 - W23.2 Secondary open reduction of fracture of bone and extramedullary fixation HFQ
- Add site code for fracture

Endoprosthesis replacement

Guidance due for publication in summer 2018

Excision arthroplasty

- W57.2 Primary excision arthroplasty of joint NEC
 - W57.3 Revision of excision arthroplasty of joint
 - W57.4 Conversion to excision arthroplasty of joint
- Add site code to all - Z81.5 Elbow joint

Replacement of infected prosthetic joint replacement first stage

- O23.4 Attention to total prosthetic replacement of elbow joint NEC
 - Y03.7 Removal of prosthesis from organ NOC
 - W81.7 Insertion of therapeutic spacer into joint
 - Y70.3 First stage of staged operations NOC
 - Z81.5 Elbow joint
- Please note: Debridement must not be coded in addition when a joint spacer has been inserted following removal of the prosthesis.

Second stage

Insertion of like for like prosthesis

Relevant revision code from list above

Y71.1 Subsequent stage of staged operations NOC

Insertion of a different type of prosthesis

O21.0 Conversion from total prosthetic replacement of elbow joint using cement

Or

O22.0 Conversion from total prosthetic replacement of elbow joint not using cement

Y71.1 Subsequent stage of staged operations NOC

HRG MAPPING WITHOUT CCs

O21 Total prosthetic replacement of elbow joint using cement

O21.1 Primary total prosthetic replacement of elbow joint using cement – HN62

O21.2 Conversion to total prosthetic replacement of elbow joint using cement – HN86

O21.3 Revision of total prosthetic replacement of elbow joint using cement – HN86

O21.4 Revision of one component of total prosthetic replacement of elbow joint using cement – HN86

O22 Total prosthetic replacement of elbow joint not using cement

O22.1 Primary total prosthetic replacement of elbow joint not using cement – HN62

O22.2 Conversion to total prosthetic replacement of elbow joint not using cement – HN86

O22.3 Revision of total prosthetic replacement of elbow joint not using cement – HN86

O22.4 Revision of one component of total prosthetic replacement of elbow joint not using cement – HN86

Lateral resurfacing replacement

W58.1 Primary resurfacing arthroplasty of joint

Z81.5 Elbow joint

HN62B

Elbow hemiarthroplasty

W52.1 Primary prosthetic replacement of articulation of bone using cement NEC – HN62

W53.1 Primary prosthetic replacement of articulation of bone not using cement NEC – HN62

W53.3 Revision of prosthetic replacement of articulation of bone not using cement NEC – HN86

Z69.7 Lower end of humerus NEC

Change of polyethylene inserts

O23.4 Attention to total prosthetic replacement of elbow joint NEC

Y03.6 Adjustment to prosthesis in organ NOC

HN63

ORIF for peri prosthetic fracture

W20.1 Primary open reduction of fracture of long bone and extramedullary fixation using plate NEC – HE82

W23.2 Secondary open reduction of fracture of bone and extramedullary fixation HFQ – HE82

Excision arthroplasty

W57.2 Primary excision arthroplasty of joint NEC – HN64

W57.3 Revision of excision arthroplasty of joint – HN63

W57.4 Conversion to excision arthroplasty of joint – HN86

Add site code to all - Z81.5 Elbow joint

Replacement of infected prosthetic joint replacement first stage

O23.4 Attention to total prosthetic replacement of elbow joint NEC

Y03.7 Removal of prosthesis from organ NOC

W81.7 Insertion of therapeutic spacer into joint

Y70.3 First stage of staged operations NOC

Z81.5 Elbow joint

HN62B

Please note: Debridement must not be coded in addition when a joint spacer has been inserted following removal of the prosthesis.

Second stage

Insertion of like for like prosthesis

Relevant revision code from above

Y71.1 Subsequent stage of staged operations NOC

Insertion of a different type of prosthesis

O21.0 Conversion from total prosthetic replacement of elbow joint using cement – UZ01Z

Or

O22.0 Conversion from total prosthetic replacement of elbow joint not using cement – UZ01Z

Y71.1 Subsequent stage of staged operations NOC