Surgical Replacement of the Temporomandibular Joint: Interim guidance for Merseyside and Wirral /Cheshire Commissioners when considering funding requests

1. Introduction
Surgical replacement of the Temporomandibular joint (TMJ) is a relatively uncommon surgical procedure with around 16 maxillofacial surgery centres in England undertaking the procedure including University Hospital, Aintree in Merseyside. Typically 15-20 such procedures are undertaken at Aintree annually with funding for the procedure currently being based on an IFR basis. The geographical spread of patients receiving this form of surgery at this centre is approximately: 50% of patients from Merseyside, 30% from Cheshire and Wirral and the remaining 20% of patients being referred from elsewhere including Staffordshire, Greater Manchester, Yorkshire and the North East.
It is expected that national guidance for commissioners to support decision making for funding requests will be developed. In the interim this guidance has been developed to support Merseyside and Cheshire and Wirral Commissioners with their decision making for funding requests. In the fullness of time this document will be superseded by national guidance.

2. Indications for TMJ replacement
The causes of TMJ disease include inflammatory and degenerative arthritis, trauma and the complications of surgery. Symptoms include pain and difficulty opening the mouth and an inability to eat a normal diet. In the most severe cases, patients cannot open their mouths adequately - dentistry, anaesthesia and resuscitation may be severely complicated and even life threatening. Pain and dysfunction associated with the condition can have a significant, detrimental impact on quality of life. In these severe cases, TMJ replacement should be considered.

Conservative treatment for TMJ disease includes the use of non-steroidal anti-inflammatory drugs, the use of non- surgical botulinum toxin therapy,
physiotherapy and pain modulating drug therapy. Surgical options include arthroscopic surgery or discectomy and replacement of components of the joint such as the disc, the fossa/socket or the mandibular condyle. Total prosthetic replacement of the TMJ is considered for patients in whom alternative treatments have failed. This procedure involves replacing the skull base component and the condyle with a prosthesis and is undertaken under general anaesthetic. A number of different prostheses are available for the procedure.

It should be emphasized that prior to being considered for TMJ replacement, that all patients would be expected to have tried the conservative methods of managing the condition. They may not necessarily have undergone other joint surgery apart from arthrocentesis and arthroscopy. MRI and/or CT scans would be used to identify the patients with the most severe joint destruction. There is evidence from case reviews to indicate that patients who have undergone joint modification surgery may subsequently have poorer outcomes should TMJ replacement subsequently be required.

3. Desired outcomes for TMJ replacement surgery

The patient would be expected to experience any or all of the following:

- Reduction in pain assessed by the patient
- Improved mouth opening
- Improved chewing and the ability to consume a normal diet
- Bite correction
- Improved quality of life

Case observation by local Oral and Maxillofacial surgeons undertaking TMJ replacement regularly, indicates that the best outcomes for TMJ replacement are found in patients were surgery has been required due to the presence of rheumatoid arthritis, ankylosis, following ablative surgery for tumour removal and post trauma. Smaller improvements are observed for patients whose main
symptom is chronic pain or those who have undergone multiple operations on the TMJ.

4. Effectiveness of TMJ replacement
A number of case reviews have been published which report on the outcomes of TMJ replacement over various time periods ranging from 3 years to 15 years. (1,2,3). These follow up studies consistently reported significant improvements in pain intensity, reduced interference whilst eating, increased maximal incisal opening in the short term period post-surgery and for the majority of cases in the medium term follow up period (3-8 years).

As outlined in paragraph 3, it appears that at the Aintree centre, better outcomes to surgery are observed for patients with ankylosis, rheumatoid arthritis, post cancer surgery and post trauma compared to those with chronic pain as the main symptom and those who have undergone multiple surgical procedures.

The evidence for longer term improvements in symptoms is less conclusive at the present time.

In 2009 NICE issued guidance on TMJ replacement (as a relatively new surgical procedure) In the absence of RCTs and a substantial body of long term case reviews around effectiveness (4), NICE issued the following advice:

- For all patients to have a pre-operative discussion and written information outlining the potential risks and benefits of the procedure
- For outcomes of surgery to be monitored long term
- For the procedure to be carried out by surgeons with appropriate training and experience in TMJ replacement

5. Contraindications to TMJ replacement:

The only absolute contra-indication to TMJ replacement surgery is the presence of active or chronic local infection

A number of other relative contra-indications are recognized. These are:

- severe immune-compromised patients
- severe coexistent diseases (American Society of Anaesthesiologists Grade III)

- patients with mental or neurological conditions who are unwilling or unable to follow post-operative care instructions;

- known allergic reaction to any materials used in the components;

- patient conditions where there is insufficient quantity or quality of bone to support the components;

- systemic disease with increased susceptibility to infection;

- patients with extensive perforations in the mandibular fossa and/or bony deficiencies in the articular eminence or zygomatic arch that would severely compromise support for the artificial fossa component;

- partial TMJ joint reconstruction;

- patients with severe hyper-functional habits (e.g. clenching, grinding etc.).

In the presence of any of the relative contraindications, a risk assessment for the procedure will be undertaken and the documentation supporting the funding request would be expected to reflect this.

Additionally, in exceptional cases TMJ replacement for skeletally immature patients may be justified and may be considered. This is expected to take place within specialist childrens hospitals as part of other craniofacial surgical reconstruction.
6. **Revision surgery:**

As with other joint replacement procedures, revision surgery is likely to be required. There are three likely scenarios

- Early revision surgery for TMJ replacement may be required where allergies develop to materials used. Skin patch testing may be required (which may require additional funding) prior to revision surgery.

- Infection can cause the TMJ replacement to fail early after surgery or some considerable time afterwards. (both of these reasons for early revision surgery are relatively uncommon)

- Revision surgery due to wear or mechanical failure of the TMJ may be required in the longer term. At the present time it is anticipated that a TMJ replacement should normally last for 10-15 years. As techniques and materials develop the time interval for revision surgery should increase.

7. **Summary of patient selection for NHS funded TMJ replacement**

Based on the NICE guidance available and the findings of published case reviews the following patient criteria should be met for TMJ replacement surgery to proceed:

- Any or a combination of the following symptoms are present:
  - Restricted mouth opening <35mm)
  - Dietary score of< 5/10 (liquid scores 0, full diet scores 10)
  - Occlusal collapse (anterior open bite or retrusion)
  - Excessive condylar resorption and loss of height of vertical ramus
  - Pain score > 5 out of 10 on visual analogue scale (**and combined with any of the other symptoms**)  
  - Other significant quality of life issues

  AND
- Evidence that conservative treatments have been attempted and failed to adequately resolve symptoms and other TMJ modification surgery (if appropriate) has also been attempted and failed to resolve symptoms.

- TMJ replacement for patients with relative contraindications may be considered where a risk assessment of the benefits of TMJ replacement has been undertaken and reported.

- Revision surgery cases where the previous TMJ replacement has failed due to long term wear / mechanical failure or where there has been shorter term failure due to infection or allergy and necessary steps / investigations have been undertaken to mitigate against the cause of failure.

References:
4. Artificial Temperomandibular Joint replacement. NICE interventional procedures guidance no 329, December2009


Review date: September 2016 (or subject to national guidance being developed).
APPENDIX 1

Guidelines for the replacement of Temperomandibular Joints

There has been an increase in the use of prosthetic replacement of temperomandibular joints (TMJ) in the United States and subsequently in the UK in recent years for specific patients. This is an expensive and technique dependent procedure and there may be serious consequences if the technique is regarded as a panacea for all TMJ conditions. The British Association of Oral and Maxillofacial Surgeons (BAOMS) requested that those surgeons who are currently using this form of surgery should liaise and formulate some guidelines for its use and those guidelines (Sidebottom A.J. - 2008) form the basis for this Appendix. The position should be reviewed in two years (2010).

Indications for total replacement of the TMJ

The indications are more stringent than those for orthopaedic total joint replacement.

Prerequisite – Failed conservative management (including arthroscopy if possible).
**Diagnosis** – Computed tomogram or magnetic resonance scan as a minimum (not just plain radiographs).

**Diseases involving condylar bone loss**

- Degenerative joint disease (osteoarthrosis)
- Inflammatory joint disease (e.g. rheumatoid, ankylosing spondylitis)
- Ankylosis
- Post traumatic condylar loss or damage
- Postoperative condylar loss
- Previous prosthetic reconstruction
- Previous costochondral graft
- Serious congenital deformity
- Multiple previous procedures

**Indications (usually a combination of the following)**

- Dietary score of < 5/10 (liquid scores 0, full diet scores 10)
- Restricted mouth opening (< 35mm)
- Occlusal collapse (anterior open bite or retrusion)
- Excessive condylar resorption and loss of height of vertical ramus
- Pain score > 5 out of 10 on visual analogue scale (combined with any of the others)
- Other significant quality of life issues

These give an idea of pain and functional disability, and permit some assessment of outcome.

**Contraindications**

See main document

**Surgical indications of hemiarthroscopy of the TMJ (fossa eminence prothesis)**

**Indications**

- Painful or dysfunctional internal derangements after failed conservative and surgical treatment, and a healthy condyle as computed tomogram or magnetic resonance scan.

- Associated quality of life issues as with total prosthetic replacement

**Contraindications**
Disruption of the condylar surface.
Avascular necrosis
Presence of osteophytes

Summary

These guidelines are not all inclusive but they do provide guidance for referral of patients for assessment for this procedure by a suitably trained and qualified surgeon. They should be revised as new developments occur and audit of the outcomes of the prostheses continue. A UK database is currently in production for analysis of outcomes.

Reference