Specialised Services Circular

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Clinical Commissioning Policy Non-Invasive Lengthening Rods for Scoliosis (Paediatrics)

Circulation

For action	For information
Area Team Directors Area Team Directors of Commissioning Area Team Heads of Specialised Area Team IFR Leads Area Team Finance Leads Area Team Pharmacists Area Teams to circulate to providers of Complex Spinal Surgery (Paediatrics): Acute Trust Chief Executives; Acute Trust Medical Directors	Regional Directors of Commissioning Regional Heads of Specialised Commissioning Regional Finance Leads Regional Medical Directors Area Team Medical Directors

Background

Non-invasively lengthening rods is an alternative treatment to standard surgically lengthened spinal rods; both of which are used to correct curvature of the spine (scoliosis). The traditional treatment for scoliosis is to partially correct the curve using instrumentation and fuse the spine in the new position. However, in young patients this results in a short spine and a reduction in thoracic volume and lung function which produces cardiorespiratory morbidity.

Over the last few years, the procedure has evolved with the option for non-invasively lengthened spinal rods to be inserted instead. Non-invasive rods minimise open surgery, which reduces the surgical risk to the patient and minimises the risk of infection.

In 2012/13 59 patients were treated with Non-invasive lengthening Rods rather than the conventional surgically lengthened Rods. The impact of applying a national policy and eligibility criteria is that 114 patient in total would benefit from this treatment for scoliosis each year in England.

The initial procedure the patient receives is the same with the non-invasive lengthening rods as it is with the surgically lengthened rods; it therefore has the same level of safety and risk at the initial surgical stage as the previous used treatment. The benefit of the non-invasive lengthening rods for patients is that the lengthening is done in an outpatient setting using a magnetic device to lengthen the rods. If they did not have the non-invasive rod then they would instead go back into hospital for a surgical lengthening procedure, increasing their risk of complication, infection; having a greater impact on a patients (and their carers) experience, quality of life and recovery time.

The evidence base was reviewed independently by both NICE and Solutions for Public Health who concluded that non-invasive lengthening rods were clinically and cost effective, in addition compared to the surgically lengthened rods they are considered to have lower infection and complication rate by NICE and from the available evidence base.

Summary

The Clinical Commissioning Policy for Non-Invasive Lengthening Rods has been recommended for approval as a routinely commissioned treatment for children and young people with scoliosis. This policy was considered against the In-year service development policy and met with the factors to support in-year funding. The policy will be subject to 12 weeks public consultation, which will commence at the end of May.

Given the significant support we have received for implementation from the Clinical Reference Group, British Scoliosis Society, and our registered stakeholders, and the potential in year QIPP savings, we are advising local area team commissioners and providers that during the consultation stage and until the policy becomes a final published policy then the policy can be applied as an interim policy.

Clinical teams can offer patients and their families either the surgical or non-surgical lengthened Spinal rods during that period; although we expected based on the feedback and poll with patient and their families that most will choose to be treated patient with non-invasive lengthened Rods.

If the patient is offered and treated with the non-invasive lengthening rods then the following clinical eligibility and commissioning intentions apply.

Overview of Patient Eligibility Criteria

The inclusion criteria are:

- Consultant Paediatric Spinal Surgeon feels that an instrumented spinal fusion will result in an unacceptable reduction in final height and respiratory function AND
- Between the ages of 2 and 11 for girls and 2 and 13 for boys. Some children are not as skeletally mature as their chronological age so a radiograph confirming bone age within the acceptable age limits is satisfactory. Use outside the specified chronological and skeletal age range may be appropriate if the patient is particularly small for age, has late development or has an increase in respiratory risk but a request should be submitted through the IFR process if an exceptional case can be set out by their clinical team.

And exclusions:

- Infection or pathological conditions of bone such as osteopenia which would impair the ability to securely fix the device
- Metal allergies and sensitivities
- Patient with Pacemaker
- Patient requiring MRI imaging during the expected period device will be implanted
- Patients younger than two years old
- Patients weighting less than 25 lb. (11.4 kg)
- Patients and/or families unwilling or incapable of following postoperative care instructions.

<u>Overview of Commissioning Intentions of the Policy</u>

As a consequence of publication of the final approved policy, surgically lengthened rods will be decommissioned except for those patients meeting the exclusion criteria for non-invasive lengthening rods. It would only be for patient whom a clinician can set out exceptional circumstances in line with the NHS England IFR policy that requests for use of the surgical lengthening Rods should be made (for those meeting the inclusion criteria).

Other similar devices will be considered for inclusion under this policy, provided they are an equal comparative device to that evaluated as part of the policy prioritisation process.

Providers will be re-imbursed following implantation of the non-invasive lengthening rods through a device exclusion. At a rate of £10,000 for a double rod system and £5,000 for a single rod. The Hospital will also claim the usual tariff for an instrumented scoliosis correction. Outpatient lengthenings will be paid at standard outpatient follow-up rate only.

NHS England are also commencing the process to add the non-invasive lengthening system to the procurement framework and discussions with manufacturers. Payment of the device exclusion will be dependent on prospective data collection which will need to be presented by providers to commissioners.

Action

The policy will become affective at the date of publication. The policy will be adopted as an interim policy until the end of the consultation period when the final policy decision will be taken after considering the consultation feedback.

Area Teams are asked to make their complex spinal surgery providers aware of the interim commissioning policy position and the terms of that policy and mechanism for funding.

The national team will develop a template CVO for area teams that sets out the commissioning and contracting terms above and share with AT heads of finance long with the supporting policy and financial assurance information WC 22/04/14.

The CRG Chair will communicate to the British Scoliosis Society the policy decision, next steps and actions for society members in the application of this policy and provision of treatment.

Further Information

Details of the current NICE medical technological guidance can be found at:

http://guidance.nice.org.uk/MT/169

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