

South Central Priorities Committees (Southampton, Hampshire, Isle of Wight and Portsmouth PCTs)

Policy Recommendation 139: Bone Morphogenetic Protein and Low-intensity Pulsed Ultrasound in Delayed and Non-Union Fractures

Date of issue: August 2012

The South Central Priorities Committee (Southampton, Hampshire, Isle of Wight and Portsmouth PCTs) has considered the evidence for low intensity pulsed ultrasound (LIPUS – marketed in the UK as the Exogen system) and bone morphogenetic protein (BMP) in the management of delayed and non-union fractures. The committee recommends the following:

1. Delayed Union Fractures

NHS funding for LIPUS and BMP should be **LOW PRIORITY**.

- Slower than expected healing (delayed fracture healing) occurs in a varying proportion of fractures depending on fracture site, complexity and other factors such as age of patient and co-morbidities.
- Published evidence of clinical effectiveness of LIPUS in delayed union is inadequate to support routine use in this indication and there is no published evidence of cost-effectiveness.
- There are no published studies of clinical or cost effectiveness of BMP in this indication. Use of BMP in delayed union fracture is beyond the licensed indication.

2. Non-union Fractures

NHS funding for BMP (specifically BMP-7, also known as OP-1 or eptotermin alfa, marketed as Osigraft) should be **RECOMMENDED** in

- Patients with established fracture non-union where previous bone autograft has failed or in whom bone autograft is not feasible. It should be noted that use of BMP-7 in non-tibial fractures is outside the licensed indication.

NHS funding for LIPUS (Exogen) should be **RECOMMENDED** where definitive surgical management (including autograft and/or BMP as appropriate) has failed to achieve union (or can be predicted to be at high risk of failure), in patients where surgical intervention is contraindicated or as part of limb salvage where the only remaining surgical option is amputation.

- This recommendation is based on strong clinical opinion based on local experience.

In view of the weakness of the current evidence base for LIPUS (Exogen) and BMP, commissioners should agree arrangements for prospective monitoring and evaluation (audit) of all LIPUS and BMP use and outcomes (in line with these recommendations) and review these recommendations in light of the results.

NOTES:

1. Exceptional circumstances may be considered where there is evidence of significant health impairment and there is also evidence of the intervention improving health status.
2. This policy will be reviewed in the light of new evidence or guidance from NICE.
3. South Central policies can be viewed at <http://www.sph.nhs.uk/priorities/policy-statements>