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Subject: Coverage of Bone Morphogenetic Proteins for use in Lumbar Fusion

To whom it may concern:

The American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) applaud the efforts of the Washington State Health Care Authority's Health Technology Clinical Committee (HTCC) in their review and analysis of the use of recombinant Bone Morphogenic Protein (rhBMP) in lumbar fusion surgeries. We strongly believe, however, that the published draft findings should be reexamined and modified.

The HTCC has voted to not cover rhBMP-7 and to cover rhBMP-2 with conditions. The conditions for coverage of rhBMP-2 include: use in the lumbar spine only, use in adults 18 years or older for primary anterior open or laparoscopic fusion at one level between L4 and S1 or for revision lumbar fusion on a compromised patient for whom autologous bone and bone marrow harvest are not feasible or not expected to result in fusion.

As noted in our original comments, we believe rhBMPs are a comparably safe and effective bone graft alternative appropriate in patients with medical indications as determined by their treating surgeon. FDA approval of the on-label indications of rhBMP noted equivalent or superior fusion rates, shorter operative times, and decreased bone graft donor site complications. Our assessment of the literature would indicate that rhBMPs are appropriate bone graft options for single level anterior and posterior lumbar interbody fusion, and can also be considered an appropriate bone graft substitute in single-level posterolateral lumbar fusion.

It is our position that the HTCC concentrated on the "on-label" use of rhBMP-2 that was originally studied in patients undergoing an interbody fusion via an anterior approach. Some of the committee's concerns regarding the safety of rhBMP-2 may actually be secondary to the choice of surgical approach; these complications, primarily retrograde ejaculation in males, are well-known and reported in the literature.

We believe that possibly safer approaches, including posterior lumbar interbody fusion, transforaminal lumbar interbody fusion, extreme lateral interbody fusion, and direct lateral interbody fusion, should be considered as appropriate surgical approaches for placement of rhBMP-2 to achieve fusion in the interbody space. Therefore, we strongly urge the HTCC to consider covering any single level lumbar fusion regardless of the surgical approach utilized to gain access to the interbody space. By restricting rhBMP use to only anterior approaches, the HTCC is denying patients a more efficacious fusion with potentially lower morbidity, since many patients are unable to safely undergo an anterior lumbar approach.

Any potential adverse effect of BMP use should be weighed against those of autograft and allograft. Iliac crest bone grafting and harvest has well-known morbidity that may be permanent. With the exception of anterior cervical spine fusion, the present literature does not support that complication rates in patients undergoing spine fusion with BMP (on label or off label) are significantly higher than those patients undergoing autograft harvest.

We support the HTCC decision regarding the use of rhBMP-2 in patients undergoing revision surgery where autologous bone and bone marrow harvest are not feasible or not expected to result in fusion. This off-label use of rhBMP-2 will allow the surgeon to determine the best treatment for these often difficult and compromised patients. We would proffer, however, that similar indications for rhBMP use may be present in non-revision cases.

Conclusion

We appreciate the opportunity to review the draft Washington State Health Care Authority's draft coverage policy for BMP for use in Lumbar Fusion. **The AANS and CNS believe rhBMP remains a viable alternative to autograft and allograft for clinically appropriate cases, as chosen by treating surgeons.** The full potential of rhBMP as an adjunct to spinal fusion cannot be determined by the current literature. It is almost certain that there are a number of patients for whom rhBMP will maximize the potential for a successful clinical outcome and restoration of an acceptable quality of life.

While we recognize that rhBMP is a costly technology and is not appropriate for the majority of spinal fusion procedures, we respectfully request that the Washington State Health Care Authority consider the following changes to the draft recommendations:

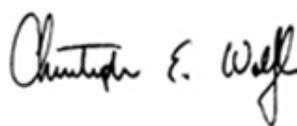
- Provide coverage for off-label use of rhBMP when clinically appropriate, as chosen by treating surgeon
- Allow for use of rhBMP in surgical approaches other than anterior lumbar interbody procedures

Thank you for considering our comments. If you have any questions, please feel free to contact John Ratliff (jratliff@stanford.edu) or Joseph Cheng, MD (joseph.cheng@vanderbilt.edu).

Sincerely,



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