PSSG Position Statement

Payor Coverage for Magnetically Controlled Growing Rods for Immature Patients with Early Onset Scoliosis

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I. Background

A posterior instrumentation system designed to provide growth friendly correction of early onset scoliosis without repeated surgical distractions (MAGEC™ - Spinal Bracing and Distraction System by Ellipse) was approved by the FDA for use on February 27, 2014. The technology has since been transferred to Globus Spine, Inc.

This technique has several benefits compared to traditional growing rods.

1. Growth-friendly correction.

Magnetically controlled growing rod instrumentation was first reported to correct spinal deformity while allowing for continued spinal growth in an immature patient in 2009, followed by subsequent larger retrospective series by other centers.[1–13]

2. Less morbidity and costs.

Traditional growing rods (TGR) require the surgeon to re-open the surgical incision site to distract the devices every 6-9 months to allow for continued normal spine growth.[14] These repeated distractions have been shown previously to increase health care costs, hospitalization days, and the risk of general anesthesia complications, wound complications, surgical complications, and psychological dysfunction.[15–17] This increase in complication risk can be mitigated by MCGR instrumentation, which allows for scoliosis patients to undergo lengthening procedures in an outpatient setting, and has a lower reported average of 1.3 surgical procedures prior to definitive fusion,[18] compared to TGR (5.1 procedures).[19]

The potential for magnetic growing rods to improve scoliosis patient outcomes under the principles of beneficence means that this device needs to be made available to those patients that meet FDA approved treatment indications and show interest in new technology.

II. The Position of PSSG

Indication: The FDA approved magnetically controlled growing rod system is appropriately restricted under the terms of the 510k pre-market approval as being indicated for skeletally immature patients with severe progressive spinal abnormalities (e.g. Cobb angle of 30 degrees or more; thoracic spine height less than 22 cm) secondary to early-onset scoliosis associated with or at risk of Thoracic Insufficiency Syndrome (TIS). TIS is defined as the inability of the thorax to support normal respiration or lung growth. Although the FDA did not require a more specific definition of “skeletal immaturity”, we believe the definition should be like those used for bracing indications. Pediatric Spine Study Group defines skeletally immature as patients Risser 2 and under OR Sanders 5 and less, as under current understanding, growth-friendly distraction depends on meaningful remaining skeletal growth. Based on recent literature, PSSG MCGR and other growth-friendly interventions, may not be best indicated in older EOS patients (> 8 years) as the surgical risks outweigh the benefits of MCGR at this stage.[9,10]

Billing/coding: Due to lack of appropriate descriptive billing codes, billing this procedure as CPT: 22899,

"Unlisted procedure; spine" with comparable instrumentation and arthrodesis comparison code(s) is a reasonable coding approach as this best describes the amount of work, skill, and RVUs associated with this procedure.[20]

Functional benefit: Clinical reports (below) indicate a potential for 1) increased spinal growth with correction of deformity, and 2) decreased hospitalizations, 3) decreased surgical complications, 4) decreased anesthesia and narcotic use, and 5) decreased caregiver burden compared to traditional growing rods. UPROR rates are reported at 27%-45% from index to graduation.[5,18,21] Additionally, PSSG believes that MCGR technology provides significant neurological and psychological promise. In 2016, the FDA released a Drug Safety Communication stating, "The repeated or lengthy (more than three hours) use of general anesthetic and sedation drugs may adversely affect children's developing brains.".[22] Thus, the practice of MCGR implantation and outpatient lengthening procedures may poise long term neurological benefits that have yet to be fully discovered.

Conclusion: The FDA has deemed the device to be safe and effective. Thus, the Pediatric Spine Study Group (PSSG) firmly concurs that payors should provide coverage for any FDA approved magnetically controlled growing rod devices, under FDA stated clinical indications and requirements, for the management of skeletally immature patients (Risser ≤ 2 or Sanders ≤ 5) with early onset scoliosis (as defined above, greater than 30 degrees Cobb angle).

III. Detailed Review of Scientific Evidence of Magnetically Controlled Growing Rods

Clinical Data

Safety and Efficacy

Extensive clinical data and experience exist demonstrating the safety and efficacy of magnetic growing rods. The papers demonstrate successful treatment across a variety of relevant outcomes including growth/height attainment, radiographic measurement of coronal deformity (cobb angle), and number of surgeries (planned and unplanned). When compared to the previous "gold standard" of traditional growing rods, magnetically controlled growing rods demonstrate equivalence or superiority.

In 2012, KMC Cheung et al. published the first case series of MCGR in humans.[1] Two patients out of five were observed at the 24-month follow-up. These two patients' preoperative coronal curve improved from 67 degrees to 29 degrees, and the sagittal preoperative curve improved from 43 degrees to 34 degrees at the 24-month follow-up. T1-T12 spinal length was observed to increase from 199 mm to 229 mm, and T1-S1 spinal length increased from 314 mm to 360 mm. The other three patients that had received MCGR implantation in this report, did not reach the 24-month follow-up at the time of publication, but all patients were observed to have curve correction and only one of the 43 lengthening procedures that patients went through lead to a loss of distraction.[1] This early human trial demonstrated the efficacy of magnetically controlled growing rods and their ability to limit the number of surgical interventions, however the study was limited by a small sample size and the technology of first-generation MCGR devices.

In 2017, Lebon et al. published a 30 patient case series of consecutive, multicenter, MCGR patients.[3] The median age at surgery was 9.1 years, and the mean follow-up in the study was 18.4 months. Mean Cobb angle was observed to improve from 66° to 44° at the latest follow-up at the time of publication. An average of 2.03 scheduled surgical procedures per patient were avoided, and an average total length gain of 21.9 mm per patient was observed. 24 complications were observed, and 13 revision surgeries

occurred in 9 patients.

In 2019, Studer et al. reported similar findings in their single-center retrospective review of 30 cases.[4] The mean age at time of MCGR implantation was 9.4 years, and 83% of the sample had a non-idiopathic EOS diagnosis. Mean follow-up time was 25 months. Mean major Cobb angle improved from 66° to 47° and mean main kyphosis angle improved from 52° to 42° at the most-recent follow-up.

In 2022, Saarinen et al. reported similar positive results in a multicenter retrospective matched comparison of 44 severe EOS (≥ 90° coronal Cobb angle) MCGR and TGR patients.[6] Mean major coronal curve improved from 104° to 52° at the 2-year follow-up, which was significantly better than the 2-year Cobb angle in TGR patients ($p = 0.001$). Kaplan-Meier analysis revealed the 2-year unplanned-revision-free survival was 91% in MCGR patients. Patient reported pulmonary function was significantly higher in MCGR patients compared to TGR at the 2-year follow-up.

In 2022, Sun et al. published a retrospective analysis of 120 cerebral palsy patients from the PSSG database.[7] They compared 86 TGR patients to 34 MCGR patients at preoperative, immediate postoperative, and at minimum 2-year follow up. MCGR produced significantly better correction at the 2-year follow up compared to TGR ($p = 0.007$), and significantly less total UPRORs ($p = 0.05$).

In 2022, Heyer et al. published a retrospective review of 189 MCGR patients, comparing primary, secondary, and converted MCGR implants.[8] No differences were observed in the major Cobb angle, T1-S1 height, or T1-T12 height over the course of the study between the primary and converted MCGR groups. The 1-year survival rate was 90.5% for primary, 84.1% for secondary, and 76.4% for converted MCGR; 2-year survival was 61.5%, 54.4%, and 41.4%, respectively; and 3-year survival was 37.6%, 36.7%, and 26.9%, respectively. Of the MCGRs that had finished expansion at the time of publication, 27.6% of primary, 8.8% of secondary, and 17.1% of converted MCGRs reached the maximum excursion. This review established that converted MCGRs have the worst survival at 2 years, and primary MCGRs have a superior survival rate.

In 2024, Grabala et al. published a multi-center retrospective review of patients with all etiologies of EOS who were treated with MCGR and had 2-year follow-up.[13] 58 idiopathic, 51 neuromuscular, 42 syndromic, and 10 congenital scoliosis patients were analyzed for a mean follow-up of 33 months following MCGR index. The mean major coronal curve of the sample improved from 86.2° (range: 65-122°) to 45.8° (range: 9-82°) at the final follow-up. All etiology groups—idiopathic, neuromuscular, syndromic, and congenital—demonstrated significant correction of the major coronal curve ($p < 0.001$), supporting the efficacy of MCGR as a growth-friendly intervention for the surgical management of early onset scoliosis across all underlying pathologies.

In 2025, Mehta et al. analyzed a series of patients from a prospective multi-center registry who had graduated from distraction-based growing rod growth friendly treatment.[12] Radiographic outcomes, complication rates, and rate of unplanned return to the operating room were compared across patients who received TGR and those who received MCGR. At the pre-definitive timepoint coronal curve magnitude ($p = 0.73$), T1-T12 length ($p = 0.71$), T1-S1 length ($p=0.56$), L1-S1 length ($p=0.40$) were similar across patients who received TGR versus MCGR. Despite having similar degrees of kyphosis across the two groups pre-index (51.7 ± 25.9° vs. 51.6 ± 24.7°; $p = 0.96$), patients who received MCGR were significantly less kyphogenic at the pre-definitive (47.9 ± 20.6° vs. 53.3 ± 23.8°; $p = 0.02$) and post-definitive (41.9 ± 18.6° vs. 47.8 ± 20.6°; $p = 0.006$) timepoints. Chi-square analysis indicated that MCGR had significantly lower rates of implant breakage ($p < 0.0001$) and overall implant related complications ($p = 0.0002$). Similarly, patients who received TGR were significantly more likely to experience an UPROR ($p < 0.001$). This study highlights over the entirety of growth-friendly intervention, MCGR is equally, if not more, effective at providing spinal deformity correction while posing significantly lower risks of

complications and unplanned reoperation.

Limits of Indications

More recently, investigators have begun to consider fusion prior to skeletal maturity (early fusion) as an alternative to management with magnetically controlled growing rods. Studies demonstrate fewer surgeries (planned and unplanned) with mostly equivalent results in height and radiographic correction of the coronal plane deformity (cobb angle). However, the use of age as inclusion criteria belies the complexity of treatment decision making. The benefits of a more complex treatment plan involving magnetically controlled growing rods over early fusion probably decrease as a patient approaches maturity but clear, universal cutoffs for this decision should not and cannot be established. Early onset scoliosis comprises a vast spectrum of underlying conditions that affect the magnitude and timing of growth, pulmonary function, chest volume (of which chest length is a component), ambulatory and physical function, and health related quality of life. The need for spinal deformity control, trunk support, and the value of incremental gains in height are thus highly individualized. Thus, the decision to utilize magnetically controlled growing rods over early fusion must be available to physicians to make in a shared decision-making capacity with the parents/caregivers of their patients.

In 2022, Mackey et al. conducted a retrospective review from a multicenter prospective registry comparing older idiopathic EOS patients, aged 8-11, that received MCGR, VBT, or fusion at index surgery.[9] The mean age of index was 10.5 years. The MCGR group was observed to be significantly younger and less skeletally mature compared to the VBT and PSF groups. Spine height and PFT results were found to be similar across groups at the final follow up. Cox proportional hazards regression adjusted for age, gender, and preoperative scoliosis curve revealed that MCGR had a significant increased hazard of requiring revision, increased hazard of unplanned revisions, and a significantly higher number of complications compared to PSF.

In 2023, Johnston et al. conducted a retrospective review of EOS patients aged 6-10 years old that received one-stage definitive fusion correction or growth-friendly intervention.[10] For the 31 patients that underwent index surgery at 8 years old or greater, the average age at index in the fusion group (N=18) was 9.5 years versus the growth friendly group (N=13) was 8.6 years. The growth friendly group was observed to have significantly greater spinal growth from preoperative to two-years postoperative as measured by T1-T12 ($p = 0.002$) and T1-S1 height ($p < 0.001$). In this older cohort, there were no significant differences in percent correction of the deformity or PFT performance at the 2-year follow-up. Older EOS patients that had received a fusion were observed to have significantly less surgical procedures ($p < 0.001$) and complications ($p = 0.016$).

In 2024, Gurel et al. investigated differences among 48 consecutive EOS patients that underwent either index MCGR surgery or were converted from VEPTR/TGR devices to MCGR. The cohort was then assessed through MCGR graduation, and post spinal fusion.[11] The mean age at index MCGR surgery was 9.1 years, and patients received a mean of 4.9 years of lengthening procedures and monitoring before undergoing fusion. Mean preoperative curve was improved from 58.1° to 36.53° prior to fusion and 27.4° at the final follow-up. Following fusion, EOS patients that underwent primary MCGR treatment experienced significantly higher major curve correction ($56 \pm 20\%$ vs. $31 \pm 34\%$, $p = 0.005$) compared to patients that were converted to MCGR. In the study sample, 11 (23%) patients sustained complications. 6 (13%) had complications requiring a single unplanned revision procedure, and 3 (6%) had complications requiring multiple unplanned revisions. This study was the largest single-center series of MCGR graduation and demonstrated the superiority of outcomes in patients that underwent primary MCGR implantation as opposed to conversion from other growth friendly instruments, and provided

further evidence of the ability of MCGR to adequately control spinal deformity and enable satisfactory growth of the thoracic spine, with a moderate complication rate.[11]

IV. Summary

In summary, a wide variety of centers and surgeons across the US, Canada, and outside North America have reproduced clinical results demonstrating acceptable safety and efficacy of magnetically controlled growing rods (MCGR) in skeletally immature patients. The FDA has judged this treatment as 'safe' and 'effective'. Given this FDA approval, the PSSG supports insurance payor coverage for FDA approved usage of such devices. There have been no published scientific reports to support the use of magnetically controlled growing rods or other growth-friendly instrumentation in treating scoliosis in skeletally mature individuals. **The PSSG does not support the use or reimbursement for posterior growth friendly MCGR instrumentation in skeletally mature individuals for the management of scoliosis or other spinal deformities**. For skeletally immature patients with early onset scoliosis who, with their parents/guardians, have selected this approach via shared decision making with their health care professionals, and have considered the risks and the benefits of continued spinal growth during deformity correction, the PSSG recommends such treatment as an insured covered benefit. For patients nearing skeletal maturity, the decision to utilize magnetically controlled growing rods versus early fusion should be available and be made solely between the physician and parent/care giver. The PSSG recommends magnetically controlled growing rod treatment of early onset scoliosis as an insured covered benefit in skeletally immature patients.

Pediatric Spine Foundation

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