DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS for MEDICARE & MEDICAID SERVICES
7500 Security Boulevard, Mail Stop AR-18-50
Baltimore, Maryland 21244-1850

Provider Compliance Group

June 3, 2021

Mark B. Leahey
President and CEO
Medical Devices Manufacturing Association
1333 H St., Suite 400 West
Washington, DC 20005

Dear Mr. Leahey,

Thank you for your letter on behalf of the Medical Devices Manufacturing Association and other healthcare stakeholders requesting that the Centers for Medicare & Medicaid Services (CMS) suspend or delay the implementation of prior authorization requirements for cervical fusion with disc removal and implanted spinal neurostimulators. We appreciate you bringing your concerns to our attention.

As part of the Calendar Year 2021 Outpatient Prospective Payment System/Ambulatory Surgical Center Final Rule with Comment Period (CMS-1736-FC), CMS added implanted spinal neurostimulators and cervical fusion with disc removal to the nationwide prior authorization process for hospital outpatient department services, effective July 1, 2021. As we described in CMS-1736-FC, as part of our responsibility to protect the Medicare Trust Funds, we continuously analyze data associated with the Medicare program. We monitor the total amount of claims or types of claims submitted by providers and suppliers and we analyze claim data to assess the growth in the number of claims over a discrete period (such as monthly or annually). Additionally, we conduct comparisons of the data with other relevant data, such as total number of Medicare beneficiaries served by providers. This analysis helps us to ensure the continued appropriateness of payment for services furnished in the hospital outpatient department setting. Based on our analysis and comparisons of claims data for cervical fusion with disc removal and implanted spinal neurostimulators, we found that the increases in volume for these services far exceed the typical baseline rate we identified. A rate of increase higher than the expected rate is not always improper; however, as we discussed in the Final Rule, after considering the data, we felt that the increases in the utilization rate for these services were unnecessary. Accordingly, CMS selected these two services for prior authorization.

To ensure that patients are not delayed from accessing care, we established a set timeframe of ten business days for contractors to complete any prior authorization request decisions, and a two-business-day expedited process in cases where the regular review timeframe or delays in care could seriously jeopardize the life or health of beneficiaries. In most cases, CMS believes there will be time to complete the prior authorization process as one of the pre-service transactions, as these procedures are not typically performed emergently. Additionally, prior authorization provisional affirmations are valid for 120 days after the date of the decision to allow physicians and hospital outpatient departments sufficient time to schedule the procedure.

As you noted, we began prior authorization for five other hospital outpatient department services in July 2020. Since CMS began prior authorization for these services, almost all Medicare Administrative Contractor (MAC) decisions have been made within the required timeframes. Given how the MACs have had the opportunity to refine their prior authorization decision-making processes, we expect they will similarly be able to make prior authorization

decisions for cervical fusion with disc removal and implanted spinal neurostimulators within the required timeframes.

To further decrease provider burden, we have implemented an exemption process for providers who demonstrate compliance with Medicare rules through prior authorization. Starting February 1, 2021, MACs began calculating the affirmation rate of initial prior authorization requests submitted for each of the five other hospital outpatient department services currently subject to prior authorization. CMS will also extend the same exemption process to providers who demonstrate compliance with Medicare rules for cervical fusion with disc removal and implanted spinal neurostimulators. Hospital outpatient department providers who have met the combined affirmation rate threshold of 90% or greater overall for all services identified on the hospital outpatient department (OPD) prior authorization list will be exempt from submitting prior authorization requests for dates of service beginning May 1, 2021.

We are continuing our preparations for the prior authorization of cervical fusion with disc removal and implanted spinal neurostimulators. We are working with the MACs to ensure that they are educating providers and stakeholders regarding these two new services, and that they are prepared to meet the required timeframes for processing prior authorization requests. Furthermore, in an effort to streamline our prior authorization requirements for these two services, we have temporarily removed Current Procedural Terminology (CPT) codes 63685 and 63688 from the list of OPD services that require prior authorization. As a result we will, at first, only require prior authorization on CPT code 63650 for implanted spinal neurostimulators services.

We believe prior authorization for these services is an effective method for controlling unnecessary increases in the volume because it reduces the instances in which Medicare pays for these services when they may not medically necessary. Prior authorization ensures that all relevant coverage, coding, and clinical documentation requirements are met before these services are furnished and before claims are submitted for payment. It offers providers provisional assurance of payment and reduces the burden of audits and associated appeals, while protecting beneficiary access to care in a timely manner.

Thank you for reaching out on this important issue. As always, we value your input as we jointly work to ensure a Medicare program that is sustainable for all and ensure that our beneficiaries have access to medically necessary and covered services. If you have other questions or concerns, please reach out to me at Connie.Leonard@cms.hhs.gov.

Sincerely,

Connie Leonard
Director, Provider Compliance

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