PUBLICATION

Medicare Proposes Prior Authorization Process for Certain DMEPOS Items [Ober|Kaler]

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On May 28, 2014, CMS issued a proposed rule to establish a permanent prior authorization process for certain durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items that are "frequently subject to unnecessary utilization." CMS defined *unnecessary utilization* as "the furnishing of items that do not comply with one or more of Medicare's clinical documentation, coverage, payment and coding rules, as applicable." Comments on the proposed rules are due by July 28, 2014.

The items to which the prior authorization process could apply are identified on a Master List being developed by CMS as part of this rulemaking. To be included on the Master List, an item must meet both a payment criteria and a risk of fraud/unnecessary utilization criteria. For the payment criteria, CMS proposes limiting the Master List to items with an average purchase fee of $1,000 or more or an average rental fee of $100 or more. For the risk of fraud/unnecessary utilization criteria, CMS proposes that the item has been identified: (i) as having a high rate of unnecessary utilization or fraud in a national Government Accountability Office (GAO) or HHS OIG report from 2007 or later; or (ii) in one of the Comprehensive Error Rate Testing (CERT) program's Annual Medicare FFS Improper Payment Rate Report DME Service Specific Overpayment Rate Appendices from 2011 or later. CMS specifically requests comments on both the payment and utilization criteria.

CMS proposes to annually publish additions to or deletions from the Master List in a notification published in the *Federal Register* and on the CMS Prior Authorization Website. Items would remain on the Master List for 10 years, although they could be removed earlier if they no longer meet the payment criteria. The proposed rule includes a proposed Master List based on the proposed payment and utilization criteria.

At least initially, the prior authorization process would be implemented for a subset of items on the Master List. CMS argues that limiting the prior authorization process is necessary to balance minimizing supplier burden with the need to protect the Medicare Trust Fund. Master List items to which the prior authorization process would apply will be identified on a Required Prior Authorization List. CMS also proposes to retain the authority to limit the prior authorization process by item to particular regions of the country. The Required Prior Authorization List would reflect all geographic limitations. The proposed rule does not include a proposed Required Prior Authorization List. Instead, CMS seeks comment on the number of items that should be selected initially and in the future and the frequency with which CMS selects those items. CMS proposes to provide 60-days notice of the Required Prior Authorization List prior to implementation in the *Federal Register* and on the CMS Prior Authorization Website.

Under the prior authorization process, a requestor would submit evidence of compliance with all coverage, coding, and payment rules before furnishing the item and submitting the claim. CMS makes a point of noting that the prior authorization process does not create any new clinical documentation requirements. Once the information has been submitted, CMS (or its contractors) would conduct a medical review and communicate a decision that "provisionally affirms" or "non-affirms" the prior authorization request. CMS cautions that provisionally affirmed claims may still be denied on the basis of technical requirements (such as duplicate claims) or information not available at the time of the prior authorization request (such as proof of delivery).

In terms of timing, CMS proposes making "reasonable efforts" to notify the requestor within 10 days of receipt of all applicable information. If the prior authorization process might “seriously jeopardize the life or health of the beneficiary,” CMS proposes to allow for an expedited review with a decision expected within 2 business days of receipt of all applicable information.

CMS asserts in the proposed rule that the decision on a prior authorization request is not an initial determination on a claim for payment, so it is not appealable. CMS will permit unlimited resubmissions of prior authorization requests, although CMS proposes taking up to 20 days to respond to such resubmissions. To pursue an appeal, an item must be furnished by the supplier to the patient, billed to Medicare, and subsequently denied.

CMS also makes clear that the prior authorization process will be mandatory where it applies. CMS will automatically deny claims for items on the Required Prior Authorization List which received a non-affirmative response to a prior authorization request or items for which no prior authorization request was submitted. Claims for items on the Required Prior Authorization List must have an affirmative prior authorization decision to be paid. Absent an Advanced Beneficiary Notice of Noncoverage (ABN), the supplier will be liable for claims for items on the Required Prior Authorization List that are submitted without an affirmative prior authorization decision.

Ober|Kaler Comments

Although patients and suppliers had hoped that a prior authorization process would be a helpful tool for establishing coverage (as it is with many private insurers), it appears that CMS views this prior authorization process as more of an enforcement tool. In introducing the prior authorization process, CMS emphasizes the importance of avoiding improper payments. CMS stops short of calling all improper payments fraud. However, rather than a coverage tool, the proposed prior authorization process seems to be an attempt to mandate the existing ADR process for certain DMEPOS items without providing appeal rights until the item is furnished and the claim is submitted and denied.

Suppliers should carefully review the proposed regulation and consider providing comments on the proposal and its likely burden on the industry. Suppliers should pay particular attention to the discussion of the time to gather and submit the applicable information with the prior authorization request. A comparison of the half-hour estimate with suppliers' experience with ADRs may be instructive.