



Accessing Essential Medications Under Medicare Part D

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By most accounts, the Medicare Prescription Drug Program is off to an uneven start. While some seniors saved money using the new benefit, others were unable to get their prescriptions filled. In some cases, the problems stemmed from computer and data issues. Pharmacies did not have sufficient information to verify beneficiary eligibility and enrollment or to bill plans. Lack of information meant some beneficiaries did not know to which plan they had been assigned or were overcharged for deductibles and co-pays. Customer service lines, pharmacy lines, and even the Centers for Medicare and Medicaid Services' (CMS) own 1-800 Medicare customer service call center were quickly overwhelmed by call volume, leaving beneficiaries, pharmacists, and doctors frustrated and angry. To avoid a crisis and to ensure continuity of treatment, in many cases, pharmacists stepped in to provide drugs without any assurance of repayment, while at least 37 states quickly ramped up emergency interventions to ensure that dual eligibles could receive their drugs without interruption.¹

Although CMS is fully engaged in trying to resolve the problems and some progress is being made, debate has erupted in the halls of Congress regarding the need for legislative interventions. At least 28 bills and resolutions have been introduced by members of Congress to fix or repeal various aspects of

the program. However, neither the Administration nor the Republican Congressional leadership are willing to concede that legislative intervention is needed.

Still, three months after the program's launch, with enrollment figures lagging behind government estimates,² beneficiaries are still having significant problems accessing medically necessary medications. In some measure, these problems stem from design of the Part D benefit itself. Because plans are being paid on a per capita basis, all plans have a financial incentive to



cut costs. Many are doing so aggressively. According to a recent report from Avalere Health, in a significant departure from typical commercial plan offerings, Medicare Part D prescription drug plans are using more utilization management controls including three-, four-, and five-tiered formularies, prior authorization, step therapy, and quantity and dosage limits.³

Although CMS has established

some guidelines to minimize disruptions in treatment as beneficiaries transition to Part D, some doctors and pharmacists are complaining that plans are employing utilization management controls to deny access to essential medications. According to Sam Muszynski, President of the American Psychiatric Association, doctors' requests to plans for prior authorization or an exception for psychiatric medications are often rejected.⁴ Long term care pharmacies that serve nursing homes and assisted living facilities also are reporting problems attaining access to frequently prescribed therapies including branded drugs and drugs when used in combination therapy.⁵ Some pharmacists predict that medication access problems will continue and may even worsen as transition periods negotiated by high volume pharmacies expire in April.

Tools for Prescribers: Understanding Coverage Determinations

Despite what appears to be a very confusing, non-system of addressing coverage issues in Medicare Part D, prescription drug plans (PDPs) are required to follow relatively clear timetables and processes for review and approval of prescription drug requests. Enrollees also have a right to appeal adverse decisions; and though the process requires several steps, it ultimately can lead to adjudication by a court of law. Understanding these rules and how to invoke them could save time, money, and even lives.

Step 1: Obtaining a Coverage Determination. In Medicare, decisions regarding drug coverage are

called “coverage determinations.” A coverage determination is *any* decision not to provide or pay for a Part D drug (including a non-formulary drug). Delay also can be considered a coverage determination if the delay would adversely affect the enrollee’s health.

An “exception” is simply a special type of coverage determination. Generally, exceptions involve a drug’s formulary position or the application of formulary management tools that restrict the drugs availability. Exceptions apply to situations when a drug is not on formulary, is on a non-preferred tier with a high co-payment, or is subject to prior authorization, step therapy, or quantity limits.

Importantly, if an exception is being sought for a non-formulary drug, a prescribing physician must provide an oral or written supporting statement that the requested drug is medically necessary. CMS’s regulations require that the physician provide a statement establishing that, in the case of a request for a non-formulary drug, all of the covered drugs on any tier of a plan’s formulary for treatment of the same condition would not be as effective for the enrollee as the non-formulary drug, would have adverse effects or both. If the request is for an exception to a step therapy or therapeutic substitution requirement, the physician must state that the alternative drug has been ineffective in the treatment of the enrollee’s disease or medical condition, it is likely to be ineffective or adversely affect patient compliance, or it has caused or is likely to cause an adverse reaction or other harm to the enrollee.

Plans must make coverage determinations, including a determination involving an exception, within 72 hours after receipt of a request. If the enrollee or the enrollee’s physician has requested an expedited determination, the plan

must respond as expeditiously as the enrollee’s health condition requires—but no later than 24 hours after receiving the request. Note, however, that the process for expediting a coverage determination is only available for requests involving a coverage issue. If the enrollee has already received the drug and the dispute is only about payment, the enrollee can still request a coverage determination; but it will be handled within the standard timeframe.

Plans must respond to coverage determination requests in writing. If the request is denied, the plan must use approved language, state the specific reasons, and give the en-



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rollee notice of his or her right to request a redetermination. If the plan does not respond within the adjudicatory timeframes, the failure is deemed an adverse coverage determination; and the plan sponsor must send the request to Medicare’s Independent Review Authority within 24 hours of the expiration of the timeframe.

Step 2: Reconsideration. Generally, an enrollee has 60 days to request reconsideration of an adverse coverage determination. The request must be made in writing. As with the initial request for a coverage determination, either the enrollee or the enrollee’s prescribing physician may request that the redetermina-

tion be expedited based on the impact of delay on the enrollee’s health. Plans must provide the enrollee or the prescribing physician with a reasonable opportunity to present evidence and allegations of fact or law, in person and in writing. For standard requests, plans have no more than seven days to issue their decision. If the request has been expedited, the plan must decide as quickly as the enrollee’s health warrants but no later than within 72 hours of receiving the request. Again, notice must be in writing, using approved language, specifying the reason for denial and explaining the enrollee’s right to further reconsideration by the Independent Review Entity (IRE).

Step 3: Reconsideration by the IRE. This is the first opportunity the enrollee has to obtain review by an entity other than the plan. The IRE is an independent agency under contract to CMS to review prescription drug coverage determinations. The IRE may solicit the reviews of the prescribing physician orally or in writing and those views must be contained in the IRE’s record.

In order for an enrollee to request an IRE’s reconsideration of a plan’s decision not to provide for a Part D drug that is not on the plan’s formulary, the prescribing physician must determine that all other drugs on the plan’s formulary for treatment of the same condition would not be as effective for the individual as the non-formulary drug, would have adverse effects for the individual or both. If the plan’s denial was based on lack of medical necessity, the reconsideration must be made by a physician with expertise in the field of medicine that is appropriate for the services at issue.

Standard IRE determinations must be made within seven days. Expedited decisions must be made within 72 hours. For Medicare Part D, the IRE contractor is Maximus.

Step 4: Appeals Process. If the decision by the IRE is adverse to the enrollee, the next step in the appeals process is requesting a hearing before an Administrative Law Judge (ALJ). The enrollees claims must be worth at least \$110 in 2006. The next step in the appeals process is the Medicare Appeals Council. Finally, if the claim is large enough (\$1090 in 2006), the enrollee may file an appeal in federal court.

If All Else Fails

CMS states that it is committed to making sure that beneficiaries under Part D get the drugs they need. To this end, they are urging enrollees and their prescribers to contact 1-800 Medicare *immediately* so that CMS case managers can intervene and help resolve issues quickly. Complaints about plans can also be filed with the Quality Improve-

ment Organization (QIO), another Medicare contractor that is authorized by statute to review complaints about quality of care.

However, it is important to note that when faced with a denial or a delay in approving a requested medication, the only action that triggers the legal requirement of a plan to respond timely and in writing is to request a coverage determination.

Conclusion

While many initial problems in the roll out of Medicare Part D are being addressed and likely will diminish over time, disputes regarding coverage of specific medications are inevitable. Whenever a dispute arises that involves access to essential medications, filing a request for a coverage determination is a critical first step in protecting and promoting the right of Medicare beneficiar-

ies to receive the medications that their doctors have prescribed. **ALC**

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From the Editor

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