MPDBM Chapter 18 - Draft Update

Comment Form

Please e-mail all comments to PartD_Appeals@cms.hhs.gov

Section number and Page number	Description of Issue or Question	Suggested Revision/ Comment
Throughout	Access to Part D drug compendium	In order to establish the medical necessity of a prescribed off-label drug, an enrollee must establish that the prescribed use is included in one of the drug compendia approved by CMS. As we stated in our comments to the proposed Part C and D regulations that we filed on January 7, 2011, beneficiaries and their prescribers do not have easy access to the compendia. We ask CMS to establish a process whereby plans must provide beneficiaries with the information they use to review off-label drug claims, including access to appropriate compendia tracts. If the use is not included in any of the compendia, then the plan should be required to certify that none of the compendia include approval for the requested use.
Throughout	Plans must provide more complete information in coverage denials.	Coverage denials, regardless of the party to whom they are provided, must include more detailed information: all reasons coverage was denied, and the information and materials necessary to satisfy utilization management requirements or other exception requests. In many cases, a plan may give one reason in an initial notice denying coverage, and it is not until a later level of appeal that the plan divulges that there is an additional reason for the adverse determination. Furthermore, in some cases, even if a plan does include language on the additional information required to overcome an adverse determination, the language is not specific or does not contain a complete list of elements. Plans should be required to include detailed, accurate, and complete information on additional materials required. This is especially important for physicians who assist patients with appeals. While some physicians may initially be willing to help, the more obstacles there are as the process proceeds, the less likely it is that a physician or an enrollee will continue with an appeal. Lastly, the reasons for a denial should be prominently featured on the first page of denial notices.
Throughout	Plans should required to provide notice both orally and in writing.	Throughout the chapter CMS states that plans may offer certain notice orally **or** in writing. Please require all notices to be given both orally **and** in writing. It is difficult to keep records of oral notices and in some cases, information provided orally may be misunderstood or may be inaccurate or incomplete. Written notices are essential to pursue appeals. While some requests to plans may begin as inquiries or grievances, they may evolve into a full appeal and it is important that there is a clear written record that may be used for that purpose.
Throughout	Please send all notices to both appointed representatives and enrollees.	It is important that both appointed representatives and the enrollees they represent receive notices. An appointed representative often works collaboratively with an enrollee and doing so can be difficult if both parties do not have copies of notices in hand. Requiring appointed representatives to mail copies of notices they receive, as faxing and even e-mail is not always an option, adds additional burdens and obstacles and also delays the progress of an appeal.

10.3.3, p 10	CMS should prohibit plans from charging fees for case files, even nominal fees for administrative costs associated with sending case files to enrollees.	Plan sponsors should not be allowed to charge enrollees for case files. In many situations the contents of case files are essential to successfully appealing plan decisions. It is often the plan that has the most complete up-to-date information on an individual's appeal. In addition, the case file may contain information to which the enrollee does not otherwise have access. In order to fully understand the basis for a plan's decision not to provide coverage, an enrollee must be able to access the information the plan used to make that decision. Lastly, requiring payment for case files will dissuade enrollees from obtaining the information and potentially appealing adverse decisions. Even small costs can be a significant hurdle for low-income individuals such as those with LIS. We ask CMS to prohibit plans from charging enrollees for case files.
10.4.1, p 12	Use of Form CMS-1696 or equivalent	Thank you for adding to the manual that plan sponsors must accept Form CMS-1696 or the equivalent.
Section 20.2.4.1 pg 23-24	Appropriate notification to consumers and their representatives about coverage and appeal rights.	CMS should require plans to provide information about the coverage determination process to individuals who call with "inquiries." The burden should not be placed on enrollees, their physicians, or appointed representatives to use the "magic words" to initiate a coverage determination. This gives enrollees additional protection, which ensures that enrollees, physicians, and appointed representatives are aware of an individual's right to initiate the coverage determination process. Furthermore, Items #4 and #5 contradict each other. Item 4 says that beneficiaries cannot request coverage determinations, but # 5 tells them that they can. We urge deleting # 4, which only causes confusion and discourages beneficiaries and their prescribers from exercising appeal rights.
20.2.4.1, p 23-24	Example concerning Actiq and non-covered drugs	
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20.3, p 27	Procedures for Handling a Grievance	The example is problematic. The information provided about Actiq is inadequate, and providing a citation to the law alone does not fully explain the off-label standard. Enrollees need to know specifically that drugs should be covered not only for on-label uses approved by the FDA but also when its use is listed in one of the designated compendia. In addition, for cancer drugs, physicians or prescribers may submit peer-reviewed literature that supports a use of a drug for a patient. This is the information most useful and meaningful to prescribers. While legal citations are necessary for appeal purposes, it is important that the information is also conveyed in plain language. This also emphasizes the need for both oral and written notices of the rules.
30, pg 29	Denials of coverage at the point of sale should be categorized as a coverage determination.	This example places an extra burden on prescribers by requiring them to use the "magic words" included in the example when they call a drug plan about a prior authorization requirement to ensure that their contact is treated as a coverage determination. Any contact with a plan sponsor by a physician or other prescriber after the enrollee is denied coverage because of a prior authorization requirement should be treated as a coverage determination. Doctors and other prescribers do not call plans to inquire about what is on the plan's formulary. They contact plans to get the medicines they prescribed covered for their patients. Their patients should not be penalized, nor should they be made to contact a plan a second time to ask for prior authorization, an exception, or a coverage determination, just because the prescriber did not state precisely that the call should serve as a coverage determination. In addition, we object to the use of Actiq as an example since Actiq, unlike many other drugs, has no compendium-supported uses other than its on-label use.

30.1, p 30	Plans are not allowed to require individuals to use specific forms to exceptions, appeals, or satisfy utilization management requirements.	We suggest that Part D plan sponsors be required to issue written responses to grievances. This provides enrollees with much needed documentation of previous experiences with plan sponsors. Physicians and representatives often struggle to determine the outcome of an enrollee's previous grievances with a plan sponsor.
30.1, p 32	Example 3 should be treated as a coverage determination	Denials of coverage at the point of sale, whether at the pharmacy counter or through a mail-order pharmacy, should be considered a coverage determination. This allows consumers to immediately initiate the appeals process and access medically necessary prescriptions in a more timely manner. Furthermore, the manual should incorporate portions of the proposed rule, should they become final, that would require notice of coverage determination and appeal rights to be given to individuals at the pharmacy. We also reiterate our recommendation that these notices be tailored to the individual to assure that enrollees are able to proceed with appeals as quickly as possible.
30.2, p. 33-34	An enrollee may not be able to access medically necessary drugs between the time of the expiration of his or her exception and the time her or she obtains a new exception from the plan.	The language used in the chapter does not accurately reflect CMS policy. A plan sponsor may not require individuals to use their specific forms to request exceptions, appeals, or satisfy utilization management requirements. Allowing plans to require a plan-specific form creates extra burdens for enrollees and prescribers and delays decisions.
30.2.1, p 35	Tiering exception	We raise the concern we raised earlier. Any call by an enrollee/physician/other prescriber to ask about a utilization management requirement should be treated as a coverage determination. This avoids placing undue burdens on the caller and will avoid delays in processing the coverage determination.
30.2.24, p 48-49	Tier placement after a request has been approved	Please allow enrollees to access transition fills of medications after the expiration of their exception. If an enrollee does not receive a new exception from the plan immediately after the expiration of the former exception, or if they must seek a new drug, it is important that his or her treatment not be interrupted, since an interruption can cause adverse health implications.
30.3.2, pg 51-52	Requiring plans to make reasonable and diligent efforts to obtain missing information	We appreciate the clarification that a beneficiary who receives approval for a utilization management exception may also request a tiering exception.
40.1, pg 54	Oral requests for coverage determinations	We request that CMS clarify that, after approving an exception request, a plan may not place the drug on a formulary tier that exceeds the cost of the drug. Plans should be allowed to have two tiers on which they may place drugs for which an exception has been granted so that a beneficiary may actually get insurance coverage for the drugs.
40.3.1, p 57	Notification by network pharmacy	This proposed change will be very helpful to beneficiaries. It is much easier for plans to obtain a missing NCD, as in the example, than for the beneficiary to obtain that information. Requiring the beneficiary to contact the pharmacy or prescriber for the information and then relaying the information to the plan adds another step and is burdensome.
40.3.4, p 59-60	Notifying consumers of plans obligations to escalate appeals if they do not meet determination timeframes set forth in law.	Thank you for adding to the manual that plan sponsors must establish and maintain a process for documenting oral requests and for retaining the documentation in the case file. We suggest you add references to HIPAA privacy requirements throughout the manual when you reference oral notification.
40.3.5; 50.5.2; 70.9.2; 70.9.4. p 62, 71, 83, 85-86	Content of written favorable decision	We renew our requests that (1) network pharmacies be required to hand enrollees notice of their appeal rights; and (2) the notice be individualized to the particular enrollee.

50.1, p 65	Request for expedited coverage determination	Plans often do not follow the requirement to escalate appeals if they do not meet timeframes set forth in law. As a result, we often forward cases to the IRE on behalf of clients or work with plans to ensure appeals are appropriately escalated. However, many consumers do not know of plans' obligations to escalate appeals if they do not meet the deadline. We believe notices should include language that explains that if plans do not meet the timeframes for appeals, cases should be automatically escalated. In addition, notices should state that if an appeal is not appropriately escalated, enrollees should report the incident to 1-800-Medicare and may escalate the case on their own. It is important that CMS properly monitor and enforce escalation requirements because the burden to escalate appeals should not be placed on consumers. As consumers often require immediate access to prescriptions, we believe that enrollees should be made fully aware of their rights.
50.5.1, p 69-70	Oral notices	We ask that CMS add a bullet that states, for formulary exceptions: The cost-sharing tier upon which the drug is placed, including the dollar amount of the cost-sharing. We also ask that CMS develop and require use of a standardized notice to ensure that all of the necessary information is provided to beneficiaries.
70.2, p 74	Clarification of time frame for requesting a redetermination	We ask that CMS add a statement that plan sponsors are required to document oral requests.
70.8, p 79	Time frame for requesting an expedited redetermination	We ask CMS to add a statement that plan sponsors are required to document oral notice of an adverse decision.
70.9.1; 70.9.3, p 8; 83-84	Content of adverse standard or expedited redetermination	Thank you for clarifying that the timeframe for requesting a redetermination runs from the date of the written notice and not from the date verbal notice is received.
70.10, p 87	Notice of forwarding case to IRE	Please add the language from Section 70.2 on page 74 that the time from the date of the written notice and not from the date verbal notice is received.
70.30, p 89	Information that must be sent as part of the case file to the IRE	The written notice must state the specific reasons for the denial. We ask that the notice inform enrollees that they may request copies of all documents the plan consulted in making the decision. As stated in our initial comment, we ask that in cases involving coverage for off-label drug use, that the plan provide the enrollee with access to the drug compendia.
120, p. 111	Abuse of the re-opening process	We ask CMS to develop a standard notice that informs the enrollee of the right to provide additional evidence to the IRE. We also ask that CMS include in this guidance a requirement that notice to the beneficiary be provided on the same day that the file is forwarded to the IRE.
120.3, p. 114	CMS should clarify if changes in policies are good cause for re-opening appeals.	We ask CMS to add a bullet to this section saying that the case file sent to the IRE must include coverage determination (including exception and prior authorization request) evidence presented by the enrollee and/or the prescribing physician or other prescriber. This will ensure that all of the information submitted by or on behalf of the enrollee will be forwarded, including the medical documentation and other information submitted to support the initial coverage determination request.
Appendix 4	Inclusion of information on the escalation of appeals.	We have concerns about the language regarding reopening cases. We believe the language should be tightened. Some plans attempt to r-open every case, seemingly without consideration of individual circumstances that would make reopening appropriate. CMS should remind plans that requesting a case be reopened is only appropriate in specific circumstances, and is not a strategy to use to try overturning all decisions favorable to the enrollees.

Appendix 12	Plans should treat inquiries specific to a drug that has been prescribed as a request for coverage and not an inquiry.	The third and second-to-last paragraph included on page 114 contradict each other; please clarify CMS's policy. The third-to-last paragraph says that reopenings based on changes in policies are not permitted, whereas the second-to-last paragraph seems to say the opposite. If changes in policy do constitute good cause, we believe that cases should only be reopened to account for the change in law if the law would favor the enrollee requesting coverage, unless such change in policy is the result of public safety concerns. If a policy changes mid-appeal, it cannot be said that an enrollee was put on proper notice of the change in rules and it is more than likely that the physician determined the appropriate treatment under the former rules.
Appendix 12	Plans should treat inquiries specific to a drug that has been prescribed as a request for coverage and not an inquiry.	Please see our comment on 40.3.4, pgs. 59-60.