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Medicare Part D

Exceptions and Appeals: A Practical Guide for Advocates

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Introduction

Medicare Part D prescription drug plans cover a limited list of drugs, known as a formulary. Beneficiaries enrolled in a plan often find that the plan does not cover drugs they need or imposes restrictions or charges high co-pays for their prescribed medications.

Enrollees have the right to challenge these plan rules. Every Part D plan must have processes in place so that enrollees can seek “exceptions” to plan restrictions. Exceptions are decided using the standard of medical necessity and require the participation of the enrollee’s physician or other prescriber. If a plan denies a request for an exception, the enrollee has the right to several levels of appeals to independent decision makers who do not work for the plan.

Advocates can help their clients negotiate the exceptions and appeals process so they can get the drugs they need. The exceptions process is also valuable for the over 2 million low-income subsidy beneficiaries who qualify for zero-premium “benchmark” plans but are currently paying premiums. In many cases, these individuals have chosen a plan that charges them a monthly premium because they could not find any benchmark plan that covers all their drugs. Using the exceptions process effectively can help these clients to stay in benchmark plans instead of paying premiums they cannot afford.

The Guide is in two parts:

1. Procedures that beneficiaries, plans and other decision makers must follow when an exception is requested and during an appeal, including those mandated by regulations adopted in 2008. These rules covering drug coverage determinations are the same both for stand-alone Prescription Drug Plans (PDPs) and for Medicare Advantage plans offering drug coverage (MA-PDs).¹
2. Substantive issues, with particular emphasis on what advocates have learned about how to address difficult issues such as coverage of off-label drugs and drugs that have not gone through full FDA approval processes.²

The Guide, designed for advocates, provides practical tips as well as statutory and regulatory requirements. Extensive footnotes direct advocates to source documents.

Please also note what is not covered in this Guide. “Exceptions” are a subset of a broader category, “coverage determinations.” Coverage determinations can also include claims related to incorrect calculations of co-payments, use of out-of-network pharmacies and other coverage

¹ See Medicare Managed Care Manual, Ch. 13 at 10 at www.cms.hhs.gov/manuals/downloads/mc86c13.pdf. Note that there are different appeals procedures for coverage determinations related to other benefits offered by MA-PDs, e.g., coverage of hospital or physician services.

² The primary document describing coverage determinations and appeals is the CMS Prescription Drug Benefit Manual, Chapter 18 – Part D Enrollee Grievances, Coverage Determinations, and Appeal (rev. 7, 2/19/09)(“PDBM, Ch. 18”) at www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/PartDManualChapter18.pdf .

disputes. This Guide does not address these non-exception coverage determinations in detail. Also outside the scope of this Guide are complaint and appeal processes related to the Low-Income Subsidy (LIS),³ to enrollment and disenrollment,⁴ and to the late enrollment penalty.⁵ In addition, a separate category, called “grievances,” addresses complaints not covered by other appeals processes. Examples of grievances include complaints about the timeliness by plans, including the timeliness of processing coverage determinations; about quality of service; about difficulties in reaching plan representatives; about general aspects of plan design, etc.⁶

For further information on Medicare Part D, please visit our website www.nslc.org, or contact Georgia Burke, GBurke@nslc.org or Kevin Prindiville, KPrindiville@nslc.org.⁷

The Procedural Basics of Exceptions and Appeals

The first section of this Guide will walk through the process for filing an exception and the five levels of appeal that are available if the exception request is denied.

I. Filing an exception

When a plan denies coverage of a drug at the pharmacy, an enrollee must either meet a Prior Authorization requirement (if the plan has imposed one for the drug) or file an exception request to get the plan to review the denial and to begin the appeals process.⁸

³ Appeal procedures for LIS applicants who apply through the Social Security Administration are found at SSA POMS HI 03040.000-03040.400.

<https://s044a90.ssa.gov/apps10/poms.nsf/subchapterlist!openview&restricttcategory=06030> Appeals procedures for LIS applicants who apply through their state Medicaid office are found in the particular state’s Medicaid State Plan. See CMS Guidance to State on the Low-Income Subsidy (May 25, 2005), www.cms.hhs.gov/States/Downloads/GuidancetoStatesonLimited-IncomeSubsidy.pdf.

⁴ CMS states that complaints regarding enrollment and disenrollment are to be handled in accordance with Chapter 3 of the Prescription Drug Benefit Manual. See PDBM, Ch.18 at 20.2.5. However, Chapter 3 does not provide detailed appeals procedures. If enrollment complaints cannot be resolved directly with plans, advocates usually bring the matter to the CMS regional office or to the CMS official who has oversight over the particular plan. Regional office email mailboxes for filing complaints are found at www.cms.hhs.gov/partnerships/downloads/11259-P.pdf.

⁵ For late enrollment penalty appeal rights and procedures, see PDBM, Ch. 18 at 80.7.1. For late enrollment penalty notices of appeal rights and appeal forms, see www.cms.hhs.gov/MedPrescriptDrugApplGriev/13_Forms.asp.

⁶ Grievance procedures, as well as how to distinguish between coverage determinations and grievances, are discussed at PDBM, Ch. 18 at 20 et seq.

⁷ This Guide, like every resource produced by NSCLC, benefits greatly from the information and experiences generously shared among members of the advocacy community. Particular thanks to Maureen Dea of Maine’s Legal Services for the Elderly for her review and helpful suggestions.

⁸ While CMS permits plans to treat pharmacy-level denials as coverage determinations that initiate the appeals process, it does not require them to do so. PDBM, Ch. 18 at 30. Plans have not generally adopted this practice. Note also that a denial of a prior authorization request does constitute a coverage determination and the plan should send the enrollee a written denial. PDBM, Ch. 18 at 30.1. The enrollee may then proceed directly to the first appeal level, redetermination by the plan.

Enrollees should use the exceptions process for the following cases:

- A needed drug is not on the plan's formulary.
- The formulary includes a Prior Authorization requirement, for example, a requirement that a blood test show a certain reading before a drug is authorized, and the prescriber could not meet it or thinks it should not apply to the enrollee.
- The formulary has a utilization management requirement, such as requiring the beneficiary to try a cheaper drug first, and the prescriber believes it should not apply, for example, because beneficiary had tried the drug in the past and it did not work well.
- The enrollee needs a larger dose or a different form of a drug (e.g. liquid instead of pills) than the formulary allows.
- The enrollee needs a formulary drug for an off-label use, i.e., a use not approved by the Food and Drug Administration (FDA).
- The drug is on a non-preferred tier on the formulary and no alternate drug on a preferred tier is appropriate for the beneficiary's condition. Drugs are placed on different "tiers" depending on how much the plan charges the beneficiary. A successful tiering exception would lower the co-payment level for a drug by treating the drug as if it were on a lower tier. See Issue 7 for more information about tiering exceptions.

In all situations, the prescriber must make a showing that the requested drug is "medically necessary." Any request for an exception *must* have the support of the prescriber.

Note: Advocates should be aware of the similarities and differences between Prior Authorization (PA) requests and exceptions. In many cases, a plan will impose a PA requirement on a drug, for example, a requirement that laboratory tests show certain values before a drug will be authorized. If a prescriber attempts to meet a PA requirement and the plan still rejects coverage for the drug, that rejection is treated as an unfavorable coverage determination that the enrollee can appeal. If an enrollee seeks coverage of a drug based on a claim by the prescriber that a PA requirement should not apply because of the particular medical circumstances of the enrollee, that request for a coverage determination is treated as an exception.

Though technically different, PA requests and exception requests involve the same steps: both require support by the prescriber and both, if unsuccessful, allow a member to start the appeal process. PA requests and exception requests are different, however, when successful. When granted, an exception provides coverage for the rest of the plan year. In contrast, plans can set the duration of a PA. In some cases PA requests must be renewed monthly, which places a significant burden on the provider.

Learn the Facts, Consider All Options

Start by getting information from the plan or pharmacist on why the plan refused to pay for the drug. Other avenues besides filing an exception may be available for your client.

- Can your client safely switch to a drug that is covered by the plan formulary? Check with the prescriber.
- Can your client change to a plan that covers his drugs?⁹ Low-Income Subsidy (LIS) recipients, for example, have a continuous enrollment period. Can he change to a plan that covers his drugs and doesn't increase his premiums? Is he otherwise happy with his current plan?
- Is the denial because the drug is a Part B drug (Part B drugs are usually administered in a doctor's office but not always)? Ask the pharmacist to process the transaction as a Part B claim. See Issue 2 below.
- Is the denial because the drug is not covered by Part D (e.g., a barbiturate or a drug for weight loss)? If your client is a dual eligible, the drug might be covered by Medicaid. If your client is enrolled in your state's State Pharmaceutical Assistance Program (SPAP), that program may be another avenue for coverage.¹⁰ Patient assistance programs run by pharmaceutical companies are another option.¹¹ For more information on non-covered drugs, see Issue 1 below.
- Did your client use an out-of-network pharmacy? Help her find an in-network pharmacy. If she has purchased the drug and is seeking reimbursement of out-of-pocket costs or if there is no available in-network pharmacy, review the plan's criteria for out-of-network access, collect the relevant facts and receipts, and request a coverage determination.¹²

Who can request an exception?

- The enrollee.
- A representative appointed by the enrollee.¹³ CMS Form 1696 or equivalent can be used to appoint a representative.¹⁴ Both the enrollee and the appointed representative must sign the CMS Appointment of Representative form.¹⁵

⁹ See NSCLC's chart of Prescription Drug Enrollment Periods at www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides

¹⁰ See www.cms.hhs.gov/States/Downloads/SPAPChart.pdf for a list of SPAPs and their eligibility requirements.

¹¹ See www.patientassistance.com.

¹² As noted above, this paper will not discuss coverage determinations concerning out-of-network access in detail.

¹³ 42 CFR §423.566(c)(3); PDBM, Ch. 18 at 10.4.

¹⁴ The form is found at www.cms.hhs.gov/CMSForms/CMSForms/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS012207. It is also available from plans.

- A representative either appointed by the court or “authorized under State or other applicable law.”¹⁶ Examples include conservators, and individuals named in a health care power of attorney.
- The prescribing physician or other prescriber.¹⁷ *NOTE: If the prescriber makes the request, no enrollee authorization is required.*
- The prescriber may also file a request for standard or expedited redetermination by the plan (the first level of appeal).¹⁸ For all subsequent appeals, the enrollee or representative must file. The prescriber may not proceed alone unless appointed as representative by the enrollee.¹⁹

Results if an exception request is granted

If an exception request is granted by the plan or at any stage in the appeals process, your client is entitled to coverage for the requested drug retroactive to the date of the earliest request or prescription purchase approved in the exception.²⁰ If your client paid for the drug, she should get her money back. If she did not purchase the drug, the plan must promptly make the drug available at appropriate co-pays. (Timeframes for making drugs available are discussed in each appeal section below.)

An exception is valid for the remainder of the plan year.²¹ A plan may, at its discretion, extend an exception beyond that period.

There are no provisions in the statute for using the exception process to obtain reimbursement of other damages caused by failure to provide the drugs or for pain and suffering. Attorneys’ fees are not available.

How to get started

To file an exception, the enrollee, enrollee’s representative or prescriber must complete and submit an exception request and submit it to the plan. Plans cannot require the use of a specific form, though many plans have a preferred form available and it may be more convenient to use the preferred form.

¹⁵ If the appointed representative is an attorney, only the enrollee needs to sign the form. The attorney’s signature is not required. PDBM, Ch. 18 at 10.4.1.

¹⁶ 42 CFR §423.560.; see also PDBM, Ch. 18 at 10.4.1. CMS has delegated to plans the determination of whether an authorization document meets state representation requirements.

¹⁷ PDBM, Ch. 18 at 10.5.

¹⁸ *Id.*

¹⁹ PDBM, Ch. 18 at 10.5 and 70.10.

²⁰ PDBM, Ch.18 at 40.2.

²¹ 42 CFR §423.578(c)(3)-(c)(4). Note, however, that if FDA subsequently raises safety concerns around the drug, the exception period may be abbreviated.

Every plan has telephone and fax numbers for filing exceptions. They are listed in the Evidence of Coverage sent to members every year and also are a prominent link on plan websites. Enrollees can also call their plan's 800 number for guidance.

Plans must accept submissions 24 hours a day, seven days a week. Requests for exceptions will not be reviewed until plans also receive a supporting statement by the prescriber. CMS has approved a general form that prescribers may use, but it is not required.²²

If the need for the drug is very urgent (24 hours or less) plans must accept oral requests for exceptions and oral support from the physician.

Timeframes for Plan Decisions on Exceptions

Once an exception is requested, the plan faces action deadlines imposed by CMS. All timeframes for exceptions begin the hour and date at which the plan receives the supporting prescriber's submission.²³

Standard Determinations:

- The plan must act within 72 hours from receipt of the prescriber's supporting statement.²⁴ The plan can require that the prescriber's statement be in writing.
- If the decision is favorable, drug coverage must be available within the same 72 hour timeframe.²⁵
- Although the plan may ask for additional information from the physician, the clock starts upon receipt of the initial supporting statement.²⁶

Expedited determinations:

- If the physician indicates, either orally or in writing, that applying the standard timeframe "may seriously jeopardize the life or health of the enrollee or the enrollee's ability to regain maximum function," the plan must grant expedited review.²⁷ On plan forms, there usually is a box for the prescriber to check.

²² See www.cms.gov/MedPrescriptDrugApplGriev/Downloads/PhysicianCoverageDeterminationRequestForm.pdf.

²³ For coverage determinations that are not exceptions, the timeframe begins upon filing by the enrollee or enrollee's representative.

²⁴ 42 CFR §423.568(a); PDBM, Ch. 18 at 40.2.

²⁵ PDBM, Ch. 18 at 130.1.

²⁶ PDBM, Ch. 18 at 30.2.2.

²⁷ 42 CFR §423.570(c)(3)(ii); PDBM, Ch. 18 at 50.1. If the enrollee requests expedited consideration but the prescriber does not attest to the need, the plan must decide whether to expedite based on the information available. A decision not to expedite can be appealed as an expedited grievance. In the alternative, the request for expedited consideration can be resubmitted with prescriber support. PDBM, Ch. 18 at 50.1-50.3.

- The plan must act within 24 hours from receipt of the prescriber's statement supporting the medical necessity of the drug or sooner if the enrollee's health requires.²⁸ Plans must accept oral statements by the treating physician. However, if the plan decides that the oral statement "does not sufficiently demonstrate the medical necessity of the requested drug," the plan may request a written statement, but must do so immediately. In such cases, the 24 hour timeframe starts on receipt of the written supporting statement. Although the plan may ask for further additional information from the physician, the timeframe is not tolled by such additional requests.²⁹ If the plan does not act within 24 hours, you should file an urgent complaint with 1-800-MEDICARE and/or the CMS regional office.
- If the decision is favorable, the plan sponsor must notify the enrollee and make drug coverage available within the same 24 hour timeframe.³⁰
- Expedited review is not available if the enrollee has already paid for and received the drug and is seeking reimbursement.³¹

Enrollees and their prescribers should keep records of the date and time of their submissions. Especially in urgent cases, it is a good idea to call the plan to verify that supporting information was received. The clock for a decision runs 24 hours per day and continues through holidays and weekends.

Many advocates tell prescribers to send supporting statements to the advocate, who then submits the documents to the plan. This procedure can make it easier for advocates to track whether a plan is meeting its deadlines.

Getting drugs while waiting for an exception to be considered

Enrollees in the following situations have the right to a temporary fill (up to 30 day supply within the first 90 days) of their prescriptions:

- New enrollees in a plan who are stabilized on a drug
- Enrollees in a plan that has changed its formulary
- Enrollees in nursing homes and other institutions (up to a 90 day supply)
- Enrollees experiencing a change in levels of care
- Enrollees who are stabilized on an off-label use of a drug that does not qualify as a "medically accepted indication" (transition period depends on the time needed to safely transition to another drug).

See our Issue Brief on Transition Requirements.³² In other cases, plans generally are not required to provide a drug while an exception is pending. However, CMS encourages plans to do so. **Ask the plan for a temporary fill.**

²⁸ 42 CFR §423.572(a); PDBM, Ch. 18 at 50.4.

²⁹ PDBM, Ch. 18 at 30.2.2 and 50.2.

³⁰ PDBM, Ch. 18 at 130.1.

³¹ PDBM, Ch. 18 at 50.

³² The issue brief is found at www.nslc.org/areas/medicare-part-d/advocate.

When a plan misses its deadline

If a plan does not meet a decision deadline, its inaction is treated as a denial of coverage and the plan must forward the exception request to the Independent Review Entity (IRE) within 24 hours of the expiration of the timeframe that the plan missed.³³ This means the enrollee can skip the step of redetermination (see below) by the plan.

The enrollee may be entitled to a temporary supply of the requested medication until IRE review is complete. **Ask the plan for a temporary fill.**

If a plan misses a decision deadline and does not forward the file to the IRE, there is no formal mechanism for a beneficiary to escalate the case to the IRE level. Advocates have found, however, that contacting the IRE and/or filing a grievance with the plan can bring results. Filing a complaint with 1-800-MEDICARE also has been an effective approach.

II. Filing an Appeal

If a plan denies an exception or a PA request, the enrollee has the right to appeal. There are five levels of appeal: redetermination by the plan, external review by an Independent Review Entity (IRE), review by an Administrative Law Judge (ALJ), review by the Medicare Appeals Council (MAC) and review by a federal court.

- **Enrollee Filing Deadlines:** For all appeals up to and including requests for review by the Medicare Appeals Council (MAC), the enrollee filing deadline is 60 days from the date printed on the notice of denial received by the enrollee.³⁴ An enrollee may file late if he makes a showing of good cause for late filing.³⁵

Level One: Redetermination

- If your client wishes to appeal a negative exception request decision, she must file a request for a redetermination, which means that a different decision maker inside the plan will review the request.³⁶

³³ 42 CFR §423.568(c)(2); PDBM, Ch. 18 at 40.4 and 50.6.

³⁴ 42 CFR §423.582(b), PDBM, Ch. 18 at 70.2, 70.8, and 100.2.

³⁵ 42 CFR §423.584(a); PDBM, Ch. 18 at 70.3 and 80.4. Examples of good cause include: death or serious illness in the immediate family; important records were destroyed by fire or other accident; the plan gave incorrect or incomplete information about when or how to request a redetermination; notice of the determination was not received or the redetermination request was sent in good faith to another government agency within the time limit but did not reach the correct plan until after the deadline had passed. See also 42 CFR §405.942(b)(2) and (b)(3) for the good cause standard for late filing with the Medicare Appeals Council.

³⁶ 42 CFR §423.580; PDBM, Ch. 18 at 70 et seq.

- Redetermination procedures are established by each plan. The letter that the plan sends denying the original exception request will give instructions on how to ask for a redetermination.
- Timeframes for redetermination decisions:
 - Standard plan redetermination: The decision deadline is 7 days from receipt of the appeal request.³⁷
 - Expedited plan redetermination: The decision deadline is 72 hours from receipt of the appeal request.³⁸ The standard for expedited redeterminations (that applying the standard timeframe “may seriously jeopardize the life or health of the enrollee or the enrollee’s ability to regain maximum function”) is the same as for expedited exceptions. As with an original exception, the prescriber’s attestation cannot be challenged by the plan.³⁹
 - If the coverage decision is favorable, the plan must notify the enrollee and make the benefit available within the same 7-day and 72-hour timeframes.

Things you should know about redeterminations.

- The prescriber may seek standard or expedited redetermination, without having to obtain written authorization from the enrollee.⁴⁰
- The enrollee or the prescriber may add information to the record when seeking a redetermination.
- The plan must provide the enrollee’s representative with all notices, decisions and other information related to the plan’s coverage determination.⁴¹

Level Two: IRE Review.

- If coverage is again denied on redetermination, your client can seek reconsideration by the Independent Review Entity (IRE).⁴² The IRE contractor, Maximus, follows its own Reconsideration Procedures Manual.⁴³
- The letter of denial from the plan provides instructions on where to file a request for IRE review.

³⁷ PDBM, Ch. 18 at 70.7.

³⁸ PDBM, Ch. 18 at 70.8.1.

³⁹ If an enrollee’s condition worsens, nothing in the rules prohibits seeking expedited consideration during the course of an appeal, even if it was not sought initially.

⁴⁰ PDBM, Ch. 18 at 10.5.

⁴¹ PDBM, Ch. 18 at 10.4.2.

⁴² 42 CFR §423.600; PDBM, Ch. 18 at 80 et seq.

⁴³ Available at www.medicarepartdappeals.com/PartDReconsiderationManual.pdf

- Timelines for IRE review:
 - Standard appeal to the IRE: The decision deadline is 7 days from receipt of the appeal request. If the decision is favorable, the plan must make the benefit available within 72 hours of receiving notice from the IRE.⁴⁴
 - Expedited appeal to the IRE: The decision deadline is 72 hours from receipt of the appeal request.⁴⁵ If the expedited decision is favorable to the beneficiary, the plan must make the benefit available within 24 hours from notification by the IRE.⁴⁶

Things you should know about IRE review

- Review by the IRE is a paper review only. There is no hearing.
- Only the enrollee or the enrollee's representative can appeal to the IRE. The prescriber can bring the appeal only if the enrollee has signed a form designating the prescriber as his or her authorized representative.
- The enrollee or prescriber may augment the record before the IRE.
- Over half of appeals to the IRE are successful.⁴⁷

Getting Extensions of Time

Extensions of filing dates can be granted upon a showing of good cause. An extension request should identify any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented him from filing a timely request or from understanding or knowing about the need to file a timely request and any other circumstances that led to the late filing.⁴⁸

Examples of good cause include: a death or serious illness in the immediate family; records were destroyed or damaged by fire or other accident; a plan gave incorrect information about how to request a determination; the request was timely sent to the wrong agency and was not redirected in time.⁴⁹

Hearing extensions and extensions of time to file briefs or supplement the record will usually be liberally granted to newly appointed advocates. Certain extensions granted to enrollees will also extend the deadline for the decision maker to issue a ruling.⁵⁰

⁴⁴ PDBM, Ch. 18 at 130.3.1.

⁴⁵ PDBM, Ch. 18 at 70.8.1.

⁴⁶ PDBM, Ch. 18 at 130.3.2.

⁴⁷ CMS Fact Sheet: Part D Reconsideration Appeals Data-2007 at www.cms.hhs.gov/MedPrescriptDrugApplGriev/07_Reconsiderations.asp#TopOfPage

⁴⁸ See 42 CFR §423.2014(d)(4) and 42 CFR §405.942(b).

⁴⁹ PDBM, Ch. 18 at 70.3 (plan); and at 80.4 (IRE); 42 CFR §423.2014(d)(4)(ALJ);. 42 CFR §423.2100(b)(MAC); 42 CFR §423.2124 (court).

⁵⁰ See, e.g., 42 CFR §423.2018(b).

Level Three: ALJ Review.

- If the IRE determination is unfavorable, you can request a hearing before an Administrative Law Judge. For ALJ review, the amount in controversy must be at least \$130 (2010 amount).⁵¹ For procedural regulations on ALJ hearings, refer to 42 C.F.R. §423.1968 et seq.
 - Timing: ALJs must issue decisions within 90 days of receipt of an appeal request.⁵² If the decision is favorable to the beneficiary, the plan must make the benefit available within 72 hours from notification by the ALJ.⁵³
 - An expedited hearing may be granted if the prescriber indicates that the standard timeframe may “seriously jeopardize the enrollee’s life, health or ability to regain maximum function.”⁵⁴ The ALJ must determine expedited status within 5 days of a request. If expedited, the ALJ must issue an opinion within 10 days of the filing of the appeal or as expeditiously as the enrollee’s health requires.⁵⁵ The ALJ may grant expedited treatment solely on the basis that expedited treatment was granted at the prior review level. If expedited consideration is needed, be sure to explicitly request it. Check with the judge’s clerk to find out if the judge requires additional support for the request.

Things you should know about ALJ hearings.

- The Office of Medicare Hearings and Appeals (OMHA) website⁵⁶ provides a description of ALJ hearings, copies of forms and basic guidance on the hearing process.
- The IRE forwards the case record to the ALJ. The enrollee can request copies of all or part of the record.⁵⁷
- The enrollee may supplement the record. The deadline for submitting new evidence is within 10 calendar days of receiving notice of the hearing. This deadline does not apply to unrepresented beneficiaries.⁵⁸
- If your client wants the ALJ to consider information about a change in her health status since the original coverage determination, the case must be remanded to the IRE for review.⁵⁹

⁵¹42 CFR §423.630 and 423.1970. PDBM, Ch. 18 at 90 et seq. The threshold amount is indexed and can rise yearly. PDBM, Ch. 18 at 90.2. The amount in controversy is calculated by looking at the enrollee’s projected costs for the drug in dispute for the plan year. However, in certain cases, costs of several disputed drugs or claims of several enrollees can be aggregated. See 42 CFR §423.1970; PDBM, Ch. 18 at 90.2 and 90.3. The 2010 amount was published at 74 Fed. Reg. 48976 (Sept. 25, 2009).

⁵² 42 CFR §423.2016(a).

⁵³ PDBM, Ch. 18 at 130.3.1.

⁵⁴ 42 CFR §423.2016(b).

⁵⁵ *Id.*

⁵⁶ www.hhs.gov/omha/Coverage%20and%20Claims%20Appeals/coverage_claims.html

⁵⁷ 42 CFR §423.2042(b). Although charging for copying is permitted, it appears to be the general practice to waive charges.

⁵⁸ 42 CFR §423.2018(b); PDBM, Ch. 18 at 90.3 (Note that, although missing from the guidance, the regulation excuses unrepresented beneficiaries from the deadline.)

Note: This requirement forces advocates and clients to make the strategic decision whether the value of updating health information outweighs potential delays in getting ALJ review.

- ALJs are not bound by CMS sub-regulatory guidance, such as program memoranda and manual instructions, but must give them “substantial deference.” Decisions must explain deviations from agency guidance.⁶⁰
- Hearings are usually by video conference or teleconference. Grants of an in-person hearing are very rare.⁶¹
- Hearings are relatively informal and do not follow the rules of evidence.⁶²
- ALJs have subpoena power, though it is used rarely in Part D hearings.⁶³
- There is no required format for written submissions to an ALJ. They can be in letter form.

Tips for ALJ hearings

- ✚ Try to have the prescriber attend. Negotiate a hearing date around the prescriber’s schedule. When possible, try to be in the same room with the prescriber.
- ✚ Work with the prescriber in advance of the hearing. Make sure that the prescriber understands the relevant standard and has seen the materials provided by the plan and the IRE about the reasons for denial. Prepare and practice with the prescriber some questions that you plan to ask and that the ALJ is likely to ask.
- ✚ Prepare a short opening statement.
- ✚ A representative of the IRE and/or the plan may attend and may bring a physician.
- ✚ Advocates report cases where the treating physician could not attend the hearing and the only medical professional attending was a physician representing the IRE or the plan. In such cases, ALJs have tended to consult the physician as an expert. If that happens, the advocate should object and request that, if the ALJ needs technical consultation, a neutral expert be appointed.
- ✚ For procedural questions, contact the ALJ’s clerk.
- ✚ ALJ opinions are not published. However, the Center for Medicare Advocacy maintains a database of Administrative Law Judge decisions at www.medicareadvocacy.org/ALJDecisions/ALJSearch.asp.

⁵⁹ 42 CFR §423.2018(a)(2).

⁶⁰ 42 CFR §423.2062.

⁶¹ 42 CFR §423.2020(b) and 42 CFR §423.2036(b) and (e).

⁶² 42 CFR §423.2036(e).

⁶³ 42 CFR §423.2036(f).

Level Four: MAC Review.

- If the ALJ issues a negative decision, you can seek review by the Medicare Appeals Council (MAC).⁶⁴ For procedural regulations governing MAC appeals, refer to 42 CFR §423.2108 et seq.
- MAC review is discretionary. The MAC may decide to simply deny review and allow the ALJ opinion to stand.⁶⁵
- Timing: Timeframes for MAC review are the same as those for ALJ review: the decision deadline is 90 days from receipt of the appeal request for a standard review and 10 days if a request for expedited treatment is granted.⁶⁶ If your client files a brief after filing the request for review, the decision deadline starts from the date the brief is filed.⁶⁷ If the decision is favorable to the enrollee, the plan must make the benefit available within 72 hours of receiving notice of the decision.

Things you should know about MAC review.

- Filing requirements and addresses are available at the OMHA website.⁶⁸
- Although only the beneficiary has the right to file an appeal with the MAC, the IRE can ask the MAC to take a case on its own motion.⁶⁹ This usually happens when the IRE believes that an ALJ's decision conflicts with statutory requirements. If the MAC takes a case on its own motion, it must do so within 60 days of the issuance of the ALJ decision.⁷⁰
- No provision in the regulations or guidance allows a plan to withhold coverage for a drug after an ALJ issues a favorable opinion, even if the MAC takes the case on its own motion. In such cases, your client should be able to demand coverage during the pendency of MAC review. However, as a practical matter, your client and her doctor will need to consider the consequences of starting on a drug regime when the possibility remains that the MAC will deny coverage on appeal.
- MAC review usually is on paper only. Although a beneficiary can request oral argument, we have not heard of any cases where such requests have been granted.⁷¹
- The beneficiary may supplement the record or make new arguments not made in proceedings at lower levels.⁷² However, if your client wants to provide new information about a change

⁶⁴ 42 CFR §423.620; PDBM, Ch. 18 at 100 et seq.

⁶⁵ 42 CFR §423.2108.

⁶⁶ 42 CFR §423.2108(a) and (d).

⁶⁷ 42 CFR §423.2120.

⁶⁸ See www.hhs.gov/omha/process/level4/index.html

⁶⁹ 42 CFR §423.2110.

⁷⁰ PDBM, Ch. 18 at 100.3.

⁷¹ 42 CFR §423.2124.

⁷² 42 CFR §423.2122. See also PDBM, Ch. 18 at 100.4

in her health status since the original coverage determination, the MAC must remand the case to the IRE for review of the additional information.⁷³ *Note: Advocates and beneficiaries need to think strategically about whether, given the particular facts in their case, updated information on the health status of the beneficiary is sufficiently critical to the favorable resolution of the case to offset the benefit of timely review by the MAC.*

- If the MAC believes that additional facts are needed or additional steps are required for implementing its decision, it may remand the case back to the ALJ. If it is more efficient, the MAC may get additional information directly.⁷⁴ The MAC has subpoena power, though we have not heard of it being used in Part D cases.⁷⁵
- No special format is required for written briefs to the MAC; briefs in letter form are acceptable.

Level Five: Federal Court.

- If the decision of the MAC is unfavorable, you can seek Federal court review, beginning with Federal District Court. The amount in controversy must be at least \$1260 (2010 amount).⁷⁶
- An appeal must be filed within 60 days of receipt of notice of a MAC decision. Extension requests must be filed with the MAC and may be granted for good cause.⁷⁷
- All rules governing Federal court proceedings apply.
- We are aware of only one Part D exceptions case that has been appealed to Federal court.⁷⁸
- Consult an attorney with experience in Federal Court before proceeding at this level.

Reopening the Record

In addition to appealing a decision, there are limited opportunities to request a reopening of the record by any of the adjudicators in the exceptions process.

- Reopening at the plan level. The beneficiary may request reopening only on the basis of clerical error. The request must be made within one year of a coverage determination or redetermination.⁷⁹

⁷³ 42 CFR §423.2122(a)(3) and §423.2126(b); PDBM, Ch. 18 at 100.4.

⁷⁴ 42 CFR §423.2122(a).

⁷⁵ 42 CFR §423.2122(b).

⁷⁶ 42 CFR §423.630; PDBM, Ch. 18 at 110. The 2010 amount was published at 74 Fed. Reg. 48976 (Sept. 25, 2009).

⁷⁷ 42 CFR §423.2134.

⁷⁸ *Layzer et al. v. Leavitt* (S.D. N.Y. No. 07-CV-11339 (GEL)). The case is still pending. See the discussion of off-label drugs at Issue 6, below.

- If an appeal already has been filed, the plan cannot reopen the record. If a clerical error is found after an appeal has been filed, either the error must be dealt with by the next level decision maker or the beneficiary must withdraw the appeal request. However, if appeals have been exhausted and clerical error is found, the plan may reopen the record.⁸⁰
- The plan may reopen the record on its own initiative within one year or, for good cause, within four years. If the original decision was unfavorable to the beneficiary, the plan may reopen the record at any time.⁸¹
- Reopening at the IRE, ALJ or MAC level. The decision maker may reopen the case within 180 days for good cause, either at the beneficiary's request or on its own motion; the record can be reopened at any time if fraud is discovered.⁸²
 - What is good cause? Good cause is “new and material evidence that was not available or known” at the time of the decision or obvious error. A change in legal interpretation by CMS is not “good cause.”⁸³
 - Note: If a case is at the IRE level or above, there are times when asking for a reopening of the record can be a quicker route to resolving a case than filing an appeal. For example, if the IRE issued an unfavorable decision based on incomplete medical records, you could ask for the record to be reopened to submit fuller documentation. This route could be faster than an ALJ appeal, where a decision can take as long as 90 days.⁸⁴
- A request to reopen the record does not stop the 60-day clock for filing appeals to the next level of review.

Addressing Specific Substantive Issues

Issue 1: Is the prescribed drug statutorily excluded from Part D coverage?

The exception process cannot be used to obtain coverage for a drug that is not covered by Part D. The following drugs are excluded by statute from Part D coverage:

⁷⁹ PDBM, Ch. 18 at 120.

⁸⁰ PDBM, Ch. 18 at 120.

⁸¹ PDBM, Ch. 18 at 120.

⁸² PDBM, Ch. 18 at 120.2.

⁸³ PDBM, Ch 18 at 120.3.

⁸⁴ Although the regulations and guidance are silent on how quickly a decision maker must act after granting a motion to reopen the record, advocates generally have not experienced undue delays once reopening is granted.

- Drugs for anorexia, weight loss or gain. Drugs prescribed for AIDS wasting or cachexia are not considered agents for weight gain and are not excluded from Part D coverage.⁸⁵
- Drugs for fertility;
- Drugs for cosmetic purposes (drugs for psoriasis, acne, rosacea or vitiligo are not considered cosmetic) or hair growth; or
- Drugs for relief of cold symptoms (medicines for asthma coughs are covered);
- Prescription vitamins and minerals (except niacin,⁸⁶ prenatal vitamins and fluoride preparations);
- Non-prescription drugs (over-the-counter);⁸⁷
- Certain anti-anxiety and anti-seizure drugs (barbiturates and benzodiazepines are the most common);
- Sexual and erectile dysfunction (ED) drugs.⁸⁸ ED drugs meet the definition of a Part D drug only when prescribed for indications approved by the FDA other than erectile dysfunction. Currently pulmonary hypertension is the only such approved indication. ED drugs do not meet the definition of a Part D drug when prescribed for an off-label use, even if the off-label use appears in a compendium. This ED exclusion is statutory.⁸⁹

Other drugs might not be covered for reasons unique to the drug:

- Methadone. Methadone is not a Part D drug when used to treat opioid dependence because it cannot be dispensed for this purpose upon a prescription at a retail pharmacy. But methadone is a Part D drug when indicated for pain. (Methadone may be covered by state Medicaid programs in bundled payment to drug treatment clinics or hospitals that dispense methadone for opioid dependence.)⁹⁰
- Compound drugs. Drugs compounded at the pharmacy, sometimes referred to as “extemporaneous compounds” present a special case. CMS Guidance states that a compound drug might consist of all Part D drugs, some Part D drugs or no Part D drugs and that a plan may cover that portion of a compound drug that qualifies as a Part D drug.⁹¹ In practice, plans refuse payment for most compound drugs and those denials are upheld on appeal. The most notable exception is when an FDA-approved non-bulk drug, e.g., a tablet, is crushed

⁸⁵ CMS Formulary Guidance, PDBM, Ch .6 , at 10.8.

www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

⁸⁶ *Id.*

⁸⁷ Note that CMS permits plans to cover certain OTC drugs if such coverage is part of a utilization management protocol, e.g., step therapy. However, plans are not required to offer such coverage.

⁸⁸ 42 USC §1395w-102(e)(2)(A), referencing 42 USC §1396r-8 (d)(2).

⁸⁹ 42 U.S.C. 1395w-102(e)(2)(A). See also PDBM, Ch. 6 at 20.1.

⁹⁰ PDBM, Ch. 6 at 20.1

⁹¹ See PDBM, Ch. 6 at 10.4

into a suspension or solution because a beneficiary needs to take the medication in liquid form. Why the distinction? Most compound drugs are made from bulk chemicals or bulk powders. FDA does not approve bulk chemicals as prescription drugs; instead, FDA approves particular forms and dosages, e.g., a 20 mg tablet of x drug. There is a statutory requirement that a drug must be approved by FDA to qualify as a Part D drug. CMS interprets that requirement as meaning that compounds created from bulk chemicals cannot be covered but those created using individual tablets or capsules as a base can have at least partial coverage.

- Other drugs may be excluded based on their use. See www.cms.hhs.gov/partnerships/downloads/determine.pdf for further discussion by CMS of specific cases of excluded drugs.

Options for Non-Covered Drugs:

- Is your client is a dual eligible? Ask the pharmacist to process the claim through Medicaid. Most state Medicaid programs cover several non-Part D drugs.⁹²
- Is your client in an enrollment period? Explore whether any enhanced plan includes the needed non-Part D drug.
- Does your client live in a nursing home? The nursing home is required to provide all necessary drugs but can seek reimbursement from the beneficiary. Nursing home residents also have a continuous enrollment period that allows them to change plans.
- Is your client Medicaid spend-down eligible (medically needy with a share of cost)? If she pays out-of-pocket for a non-Part D drug, the payments can count as an “incurred medical expense.” If she joins an enhanced plan, premium payments also can count as incurred medical expenses.
- Explore whether you client can get the drug through a manufacturer’s patient assistance⁹³ program or, if applicable, your state’s SPAP.⁹⁴

Issue 2: The drug may be a Part B drug.

Determining whether a drug is covered by Part B or Part D can be difficult. If covered by Part B, the prescribed drug is excluded from Part D coverage.⁹⁵ The exception and appeals process can be used to challenge a plan’s determination of whether a drug is covered by Part B or Part D.

⁹² HHS Office of Inspector General, Dual Eligibles’ Transition: Part D Formularies’ Inclusion of Commonly Used Drugs (Jan. 2006), p. 14, www.oig.hhs.gov/oei/m.asp#medicare_benefits.

⁹³ An easy-to-search site covering multiple patient assistance programs is found at www.patientassistance.com.

⁹⁴ See www.cms.hhs.gov/States/Downloads/SPAPChart.pdf for a list of SPAPs and their eligibility requirements.

⁹⁵ 42 USC §1395w-102(e)(2)(B).

- Part B drugs can include drugs furnished “incident to” a physician’s services; certain oral anti-cancer drugs; immunosuppressant drugs incident to a transplant that took place when a beneficiary qualified for Medicare Part A; some vaccines, and others. See Medicare Parts B/D Coverage Table at www.cms.hhs.gov/Pharmacy/Downloads/partsbdcoverageissues.pdf.⁹⁶
- If the pharmacist can determine from information included in the prescription, such as diagnosis information or location of administration, whether Part B or Part D coverage is appropriate, the plan may rely on the pharmacist when determining appropriate coverage without the need to separately contact the prescriber.⁹⁷
- Beneficiaries who are not enrolled in Medicare Part B will still be denied coverage under Part D for a drug if that drug would have been covered had they enrolled in Part B.⁹⁸

Issue 3: The prescribed drug is a Part D drug but is not on the plan’s formulary, or is subject to utilization management or dosage limits.

The exception and appeals process can be used to obtain coverage of a drug that is off formulary or is subject to utilization management. To be successful, you will have to demonstrate your client can meet the relevant standard.

*Legal standard for non-formulary drugs: The requested drug is medically required and other on-formulary drugs will not be effective because all covered Part D drugs on any tier of a plan’s formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects. 42 CFR §423.578(b)(5)(i); PDBM, Ch. 18 at 30.2.2.*⁹⁹

Legal standard for establishing that therapeutic substitution or step therapy requirements are not appropriate for the enrollee: The requested drug is medically required and the prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements: (a) has been ineffective in the treatment of the enrollee’s disease or medical condition or, based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance; or (b) has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee. 42 CFR §423.578(b)(5)(ii); PDBM, Ch. 18 at 30.2.2.

⁹⁶ See also Medicare Part B versus Part D Coverage Issues at www.cms.hhs.gov/PrescriptionDrugCovGenIn/Downloads/PartBandPartDdoc_07.27.05.pdf. Coverage tables are also found at PDBM, Ch. 6, App. C-1 and C-2.

⁹⁷ See “Clarification of Plan Due Diligence in Prior Authorization of Part B versus Part D Coverage Determinations” at www.cms.hhs.gov/PrescriptionDrugCovContra/downloads/DueDiligenceQA_03.24.06.pdf. See also PDBM, Ch.6 at 20.2.2.

⁹⁸ PDBM, Ch. 6 at 20.2.

⁹⁹ See also 42 USC §1395w-104(h)(2).

- Educate the prescriber about why coverage was denied and what legal standard must be met. Make sure she is aware of what similar drugs are on the formulary and what utilization management requirements are in place.
- The prescriber’s statement should include information on the patient’s condition and its severity. Other drugs tried or the reasons they were not tried is critical. Prescribers may also submit journal articles and similar documents supporting the proposed use, if appropriate. A supporting statement provided by a prescriber is entitled to “great weight.”¹⁰⁰
- CMS’s guidance directs plans that, if they request additional supporting documents, they should “clearly identify” the type of information that should be submitted.¹⁰¹
- If the plan approves an exception for a non-formulary drug, the plan may place the drug co-payment level at any tier, except that, if the plan has a specialty tier, the drug may not be assigned to that tier.
- If the exception involves waiver of a utilization management requirement for a drug that is on-formulary, the drug will be approved on its original tier. However, if the drug is on a non-preferred tier, the enrollee may be able to then request a tiering exception (see Issue 7 below).
- Practice Tips:
 - Note whether your client’s prescription is for a drug in one of the six classes of clinical concern (immunosuppressants, antidepressants, antipsychotics, anticonvulsants, antiretrovirals, and antineoplastics). Plans must cover “substantially all” drugs in these categories. Further, plans may not impose step therapy requirements for any individuals already stabilized on any drug in these categories.¹⁰² If your client is stabilized on one of these drugs, submission of a physician’s statement reporting that fact should be sufficient to bypass step therapy requirements without the need to make a full “medical necessity” showing. CMS also has told plans that it is usually inappropriate to impose any utilization management requirements for HIV/AIDS medications, whether or not an individual is already stabilized on a drug.¹⁰³
 - If your client’s medication is subject to a Prior Authorization requirement that is onerous, consider filing an exception request, even if the beneficiary can meet the Prior Authorization criteria. For example, a PA requirement may demand a showing by the prescriber monthly, an undue burden if your client’s needs are not going to change.
 - If the enrollee is a dual eligible or otherwise in an enrollment period, consider changing to a plan that does not impose utilization management requirements for the drug.

¹⁰⁰ PDBM, Ch. 18 at 30.2.1 and 30.2.2.

¹⁰¹ PDBM, Ch. 18 at 30.2.1 and 30.2.2.

¹⁰² PDBM, Ch. 6 at 30.2.5.

¹⁰³ *Id.*

- CMS reports that almost 60% of exceptions related to Prior Authorization or other utilization management requirements are reversed on appeal to the IRE.¹⁰⁴ Perseverance pays.

Issue 4: The dosage prescribed exceeds the dosage limits imposed by the plan.

The exception and appeals process can be used to obtain a dose of a drug that is higher than the dosage limit set by the plan or to obtain a drug in a different form than is covered by the plan, e.g. liquid instead of tablet. To be successful, you will have to demonstrate that your client can meet the relevant standard.

Legal standard: The number of doses available under a dose restriction “(a) Has been ineffective in the treatment of the enrollee’s disease or medical condition or, (b) Based on both sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug’s effectiveness or patient compliance.” 42 CFR §423.578(b)(5)(iii), PDBM, Ch. 18 at 30.2.2.

- Both a limit on dosage form (e.g., tablet when the enrollee needs liquid) and a quantity limit may be appealed as an exception.
- Exception requests related to dosage limits are governed solely by the medical necessity standard. If a prescriber can show that a particular dosage is medically necessary for the enrollee’s condition, the plan is not permitted to require compendium support for that dosage, even if the dosage is above FDA limits.¹⁰⁵ In other words, exceeding a dosage limit by itself does not put a prescription drug claim in the “off-label” category (see Issue 5 below).
- Although exceeding quantity limits does not, of itself, put a drug in the off-label category, quantity limits often help plans to detect prescriptions for indications that are off-label. Thus a plan may first deny coverage because a prescription exceeds a dosage limit but, after reviewing the physician’s supporting statement, the plan may note that the use is for an off-label indication and expand the basis for its denial to include a claim that the drug is not a covered Part D drug for that indication (see Issue 5 below).
- CMS does not require plans to identify dosage limits on their formulary if those limits are the same as set by FDA. For this reason, beneficiaries who choose a plan specifically because the plan’s formulary has no utilization management requirements for their drugs are sometimes surprised to have their dosage rejected at the pharmacy.

¹⁰⁴ See www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/ReconAppealsData06.pdf .

¹⁰⁵ PDBM, Ch. 6 at 10.6.

- If the enrollee is a dual eligible, is receiving the Low-Income Subsidy (LIS or “Extra Help”), or otherwise is in an enrollment period, consider changing to a plan that does not impose dosage limitations for the drug.¹⁰⁶
- CMS distinguishes between dosage limits and safety or refill edits, which prohibit enrollees from refilling a prescription too soon. Refill edits generally are not subject to the exceptions process. Advocates have noted that some plans place tighter limits on refill quantities toward the end of the plan year.

Making a Showing of Medical Necessity What Should a Prescriber’s Statement Include?

Key to any exception request is the prescriber’s supporting statement of medical necessity. Ideally, a prescriber’s statement should address all the following questions:

- What condition is the drug being prescribed for? What other conditions affect the individual’s health?
- Have other on-formulary drugs been tried? Have they failed?
- If they were not tried, what was the reason?
- What documents support the choice of medication? Which medical records? Is supporting medical literature (journal articles, etc.) available?

Issue 5: The medication is prescribed for an off-label use.

The exception and appeals process can be used to obtain coverage of a drug for an off-label use. To be successful, you will have to demonstrate that your client can meet the relevant standard.

Legal Standard: There must be a showing of “medical necessity,” which means that you must meet the standard for Issue 3 and a showing that the drug is prescribed for a “medically accepted indication.” 42 USC §1395w-102(e)(4).

- Plans must cover drugs prescribed for a use that is off-label (a use not approved by the Food and Drug Administration) if certain criteria are met.¹⁰⁷ As with off-formulary drugs, there must first be a showing of medical necessity. In addition, the drug must be prescribed for a “medically accepted indication.” The kinds of supporting medical literature on which a

¹⁰⁶ See NSCLC’s chart of available enrollment periods at www.nsclc.org/areas/medicare-part-d/part-d-library/Tools-for-Advocates/Guides.

¹⁰⁷ For a discussion by CMS of its regulations governing off-label use in Part D, see 70 Fed. Reg. 4260-4261 (Jan. 28, 2005).

beneficiary can rely to show use for a medically accepted indication are broader for drugs prescribed to treat cancer than for drugs prescribed to treat other conditions.

- For all drugs, except those prescribed to treat cancer, CMS regulations provide that a “medically accepted indication” means that either the use has been approved by FDA, or the use is supported by a citation in one of three compendia:
 - American Hospital Formulary Service Drug Information
 - United States Pharmacopoeia-Drug Information
 - DrugDex Information System. *Note: Advocates report that DrugDex is usually the most helpful in supporting an off-label use.*^{108 109}
- For drugs and biologicals used in an anti-cancer chemotherapeutic regime only, other sources also can be used to demonstrate that a use is for a “medically accepted indication” including: peer-reviewed journals and additional compendia designated by CMS.¹¹⁰ A list of compendia accepted by CMS for cancer drug indications is found at the Medicare Benefit Policy Manual, Ch. 15 at 50.4.5(B). See www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.¹¹¹ A list of journals accepted by CMS is found at 50.4.5(C).
- Access to the compendia can be difficult. They are on-line but only with a costly subscription. Many large university libraries, most medical schools and many hospitals have subscriptions to the compendia.
- Compendium listings can be difficult to decipher. CMS has developed guidance on how to evaluate claims that a particular compendium listing or a peer-reviewed journal article supports usage for a particular enrollee. For example, a listing as Class I, Class IIa or Class IIb in DrugDex demonstrates a medically accepted indication, while a Class III listing does not. Although this guidance is only directly applicable to cancer drugs, the portions related to compendia are helpful in analyzing the strength of any off-label claim based on a compendium listing. See Medicare Benefit Policy Manual, Ch. 15 at 50.4.5(B) and (C), www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf.

¹⁰⁸ Tracing the basis on which CMS claims a statutory exclusion of drug uses not found in the compendia requires a close reading of multiple statutory references. 42 USC §1395w-102(e)(1)(A) states that a “covered Part D drug” means “a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A) (iii) of section 1396r-8(k)(2) of this title [42 USC §§1396r-8(k)(2)(A)(1) through (A)(3)].” The referenced subparagraphs include all FDA approved drugs and do not impose the compendium requirement. However, the introductory qualifier to those subparagraphs says “Subject to the exceptions in paragraph (3), the term ‘covered outpatient drug’ means—.” The exceptions in paragraph (3) exclude drugs “used for a medical indication which is not a medically accepted indication.” 42 USC §1396r-8(k)(6) provides a definition of “medically accepted indication,” which leads to the compendia. CMS based its regulation, 42 C.F.R. §423.100 on this statutory language.

¹⁰⁹ A case challenging the CMS regulations as contrary to statutory intent is pending in Federal District Court. *Layzer et al. v. Leavitt* (S.D. N.Y. No. 07-CV-11339 (GEL)).

¹¹⁰ 42 U.S.C. 1395w-102(e)(4)(A).

¹¹¹ See also the CMS website on the status of pending requests to add compendia for cancer drug evaluations. www.cms.hhs.gov/CoverageGenInfo/02_compendia.asp#TopOfPage and the Medicare Benefit Policy Manual , Ch. 15 at 50.4.5. www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf for a list of accepted peer-reviewed journals.

- Sometimes contacting the manufacturer of the drug may be helpful. The manufacturer might be able to provide useful background or references.
- During the course of an appeal, advocates should recheck compendia for updates. Also try to find out if a use has been approved for publication, even if not yet published.
- Off-label cases can be difficult and pursuing an appeal to the ALJ level is often necessary.
- As noted previously, there is a statutory prohibition of coverage for any off-label use of erectile dysfunction(ED) drugs. Currently the only FDA approved use of ED drugs (other than for ED, which is prohibited) is for pulmonary hypertension. This is the only usage that will qualify for Part D coverage.¹¹²
- If your client is already taking a drug and a plan then denies coverage because the plan believes that the use is not for a “medically accepted indication,” CMS guidance provides support for a request for a transition supply of the needed medication. In its guidance on off-label use, CMS specifically told plans that the agency “expects the plan sponsor to consider the enrollee’s health situation and continue to cover the drug to the extent it determines that doing so is necessary to avoid risk to the enrollee’s health while providing for a transition to another form of treatment.”¹¹³ If your client has a serious need for transition supplies and you cannot get cooperation from the plan, you can ask that your request be treated as an exception and appeal the plan’s decision. Note that the guidance is not specific about the length of potential transition coverage.¹¹⁴ Some advocates have also found that asking the CMS regional office to intervene has helped resolve a short-term emergency need for transition drugs.

Issue 6: DESI drugs, “grandfathered” unapproved drugs, “wrap-up” drugs, non-matched NDC list drugs.

The definition of a covered Part D drug includes a drug approved by FDA and, if it has not been approved by FDA, a drug “which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act.” 42 USC 1395w-151(a)(2).

¹¹² See Issue 1 above.

¹¹³ PDBM, Ch. 6 at 10.6.1.

¹¹⁴ We know of one case where an enrollee, on appeal to the IRE, was successful in getting a transition for more than three months. The treating physician supported the request with a detailed description of what was being done to move the enrollee to other medications, the time necessary for a safe transition, and the serious dangers to the health of the enrollee if the transition were undertaken on a faster schedule.

- Some prescription drugs are marketed in the United States without having gone through the usual approval process at the U.S. Food and Drug Administration. These drugs include some that have been sold in one form or another prior to 1962, the year in which FDA’s current regulatory requirements were adopted.¹¹⁵ Other drugs have been approved by FDA for production by some manufacturers but not by others. Which of these drugs could qualify as a covered Part D drug is a difficult issue.
- Because many of these drugs are covered by insurers in their non-Medicare plans, coverage issues may arise when people stabilized on one of these drugs join Medicare for the first time.
- DESI drugs are drugs that FDA reviewed for safety prior to 1962 under the then-controlling regulatory scheme but that have not been reviewed for effectiveness. FDA is in the process of undertaking effectiveness reviews of these drugs under current law. When a particular review is complete, FDA publishes a finding in the Federal Register that either approves the drug or determines that the drug is Less Than Effective (LTE).
- CMS requires that, if FDA publishes a finding that a DESI drug is LTE, plans must remove the drug from their formularies. DESI drugs that are LTE are not covered Part D drugs.¹¹⁶ The exception and appeals process cannot be used to get coverage for a DESI drug that is LTE.
 - DESI drugs that are in the process of a compliance review but have not been subject to a final determination by FDA may still be marketed. If a plan denies Part D coverage for a DESI drug that is in the process of a compliance review or that has not yet begun a compliance review, advocates should utilize the exception and appeals process, arguing that, because the drug has not been subject to a final FDA determination, Part D coverage is permitted.
- Non-DESI pre-1962 drugs are another category, sometimes referred to as wrap-up drugs. These may be “grandfathered” drugs if they are “identical, similar to or related” to drugs marketed prior to 1962. FDA does not maintain a public list of these drugs and has not issued any formal findings about whether a particular drug is grandfathered. If a drug is grandfathered, then it can be a covered Part D drug.
 - The exception and appeals process can be used to establish that a drug is grandfathered and, therefore, covered by Part D. The MAC found that one such drug,

¹¹⁵ For background on the regulatory status of pre-1962 unapproved drugs, see FDA Compliance Policy Guide, §440.100 (2006). www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070290.pdf, and “The Unapproved Drug Universe” (FDA PowerPoint presentation, 2007), www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/Selecte dEnforcementActionsonUnapprovedDrugs/ucm119959.pdf.

¹¹⁶ PDBM, Ch. 6 at 10.9.

- tincture of opium, was grandfathered based on the drug's inclusion in a list in US Pharmacopoeia.¹¹⁷
- Advocates can also argue that a CMS decision maker does not have to make a finding that a drug is grandfathered. Based on the statute, they can argue that it is enough to make some showing that the drug has been marketed prior to 1962 and that there has been no FDA finding that the drug is not grandfathered.
 - Some drugs may appear on a “Non-Matched NDC Drug List.” Beginning in 2010, CMS is requiring plans to have formulary edits for drugs with National Drug Code (NDC) numbers that are on a “non-match” list, which was prepared by CMS with the cooperation of FDA. Because the non-match list only began in 2010, advocate experience with the issue, to date, has been limited.
 - In many cases, the issue can be resolved by working with the pharmacy to get the same drug from a different manufacturer. CMS has prepared a fact sheet discussing consumer options. See www.medicare.gov/Publications/Pubs/pdf/11453.pdf
 - In some cases, the issue may be more complex. Advocates should be aware that CMS has told plans explicitly that appearance on the list is not determinative of whether a drug is a covered Part D drug but is only the start of an inquiry. See www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/MemoNonMatchedNDCList_10.21.09.pdf
 - Remember that in all cases, you also need to show that the drug is medically necessary for your client.

Issue 7: The drug is approved but the enrollee seeks a tiering exception.

Standard: The preferred drug on the plan's formulary for the treatment of the enrollee's condition: (1) would not be as effective as the requested drug; or (2) would have adverse effects. 42 CFR §423.578(a); PDBM, Ch. 18 at 30.2.1.

- A tiering exception allows an enrollee to pay for a drug at a lower co-payment tier than the tier on which the drug appears on the plan formulary. A tiering exception may be used to move a brand drug from a non-preferred brand tier to a preferred brand tier or to move a generic drug from a non-preferred generic tier to a preferred generic tier.
- A tiering exception may not be granted to move a brand drug to the generic tier. Further, plans are permitted to maintain a specialty tier for very high cost items that is ineligible for the tiering exception process. *NOTE: This means that for plans with four tiers, the tiering exception usually only is available for a move from the third tier to the second tier.*

¹¹⁷ A redacted copy of the MAC decision is at www.medicareadvocacy.org/ALJDecisions/1-426833518.pdf.

- Tiering exceptions can be used in conjunction with formulary exceptions involving utilization management requirements or dosage limits. If your client has won a formulary exception for an on-formulary drug (e.g., obtained an exception from a step therapy requirement) that is on a non-preferred tier, she may then seek a tiering exception if there is another drug on a preferred tier that will not work as well. If your client has won a formulary exception for a non-formulary drug, the tiering exception is unavailable.¹¹⁸
- Because all individuals receiving the Low-Income Subsidy only have two payment tiers, the tiering exception generally is not relevant to this population.
- Few beneficiaries understand that they can request a lower co-payment level for a medically necessary drug. In 2006, less than 2% of appeals have involved tiering exceptions. Of those filed, 30% were successful.¹¹⁹

Practice Tip

Tiering exceptions offer an underutilized opportunity to protect beneficiaries from high co-payments. This is especially true for enrollees who have won an exception from a utilization management requirement but find that the drug they need is still expensive because of its placement on a non-preferred tier. Since these enrollees have already shown the medical necessity of the drug for their condition, they and their advocates should find that the paperwork burden of filing a tiering exception is relatively small. More aggressive use of tiering exceptions could bring significant savings to many enrollees.

Conclusion

The Medicare Part D exception and appeals process is a critical part of the Medicare Part D program but is not used as frequently as it should be. Knowing what it required makes the process easier for both the enrollee and the prescriber. Advocates who are familiar with the process can be of invaluable help to their clients in navigating the system and getting coverage for medications they need. Because appeals have a relatively high rate of success, over 50%, persistence in staying with the process through the IRE or ALJ level can frequently yield positive results. We hope this Guide will encourage more advocates to use the exception process and will give them tools to do so efficiently and effectively.

¹¹⁸ 42 CFR 423.578(c)(4)(iii). Although it might seem more efficient to request a tiering exception at the same time you are requesting a formulary exception for an on-formulary drug, we have not seen this done.

¹¹⁹ See www.cms.hhs.gov/MedPrescriptDrugApplGriev/Downloads/ReconAppealsData06.pdf.

Resources

Statutes, Regulations and Guidance

Statute: Title 18 of the Social Security Act, www.ssa.gov/OP_Home/ssact/title18/1800.htm
Part D sections start at Section 1861D-1 (42 U.S.C. 1395w-101 et seq).

Regulations: 42 CFR §423 et seq. http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=946a2ca4658a3cb55b8c977cf2dd291c&tpl=/ecfrbrowse/Title42/42cfr423_main_02.tpl

CMS Guidance: Prescription Drug Benefit Manual, particularly Chapter 6 (Formularies) and Chapter 18 (Coverage Determinations and Appeals).
www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage

CMS Resources

CMS Appeals Page: www.cms.hhs.gov/MedPrescriptDrugApplGriev/11_Guidance.asp

Office of Medicare Hearings and Appeals (OMHA) Website: www.hhs.gov/omha/index.html

Advocacy Resources

NSCLC Website: www.nsclc.org

Medicare Rights Center, *Medicare Part D Appeals: An advocate's manual to navigating the Medicare private drug plan appeals process* (Mar. 2009). This is an excellent and practical resource filled with tips on how to proceed with an effective appeal.

www.medicarerights.org/pdf/partd_appeals_manual.pdf

Center for Medicare Advocacy, Database of ALJ/MAC Decisions
www.medicareadvocacy.org/ALJDecisions/ALJSearch.asp