Hospice and Part D Guidelines and Explanation

7/24/2014

On July 18, 2014 CMS released revised guidance to hospice providers and Part D plan sponsors -- Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice -- under which Part D plans are instructed to place beneficiary-level prior authorization (PA) on four categories of drugs (anti-anxieties, antiemetics, laxatives, and analgesics) as opposed to all drugs processed through Part D for patients enrolled in hospice care . This guidance replaces that previously laid out by CMS (see March 10, 2014, Part D Payments for Drugs for Beneficiaries Enrolled in Hospice – Final 2014 Guidance.) The effective date of the prior authorization (PA) policy outlined in this most recent memo is immediate with the expectation that all Part D sponsors will have it in place no later than October 1, 2014. It is anticipated that some plans will be able to incorporate the policy changes in their processes in relatively short order, while others may require the full implementation time frame to comply. The guidance is just that – guidance – and it is in effect until something more permanent is identified. In essence, this means that the policy does not hold the full force of a regulation in terms of CMS' enforcement capabilities, but CMS does strongly encourage both Part D plans and hospices to abide by the guidance and has built the policy with incentives to do so in mind.

CMS is strongly encouraging hospice providers to supply a compassionate "first fill" for any medication in the four classes for any beneficiary who is experiencing difficulty in accessing the drug at point of sale (POS). If the drug provided is unrelated to the terminal illness and related conditions, the hospice provider should contact the Part D sponsor to negotiate recovery of the hospice's payment to the pharmacy at a later date.

What Is The Prior Authorization Process?

CMS instructs the Part D plan sponsors (sponsors) to place beneficiary-level PA requirements on only four classes of drugs for beneficiaries who have elected

hospice to determine whether the drugs are coverable under Part D. These four classes are:

- analgesics,
- antinauseants (antiemetics),
- laxatives, and
- antianxiety drugs (anxiolytics).

CMS expects that most of the medications in these categories would be related to a hospice patient's principal diagnosis or related conditions so it would be a rare occurrence that one of these types of medications would be submitted to the Part D plan for payment for a hospice beneficiary.

For medications that fall into one of the four categories listed above and are determined to be related to a patient's terminal or related conditions, the Part D plan sponsors will still look to the prescriber or the hospice to make the decision on whether a drug should be covered by the hospice under Medicare Part A or the beneficiary is responsible to pay for the drug.

Drugs prescribed for beneficiaries who have elected the hospice benefit that are unrelated to the terminal illness and related conditions continue to be subject to standard Part D formulary management practices, including quantity limitations, step therapy, and prior authorization that have been approved by CMS.

The PA process is a determination of payment responsibility for drugs for hospice beneficiaries. There are three scenarios for payment responsibility

1. The hospice pays for drugs covered under the Hospice Benefit
2. The beneficiary pays for the drugs
3. The sponsor pays for the drugs covered under the Part D Benefit

Hospice Pays for Drugs Covered Under the Hospice Benefit

Hospices are reminded that they are responsible for all medications that are reasonable and necessary for the palliation and management of the terminal illness and related conditions. This includes medications the patient may have been on for some time prior to the election of hospice care as well as new medications. It also includes medications that may not be on the hospice's formulary. A hospice can require the patient to try a formulary medication if no medical reasons exist that would indicate the patient should not try the formulary medication.

The Beneficiary Pays for the Drug(s)

A beneficiary is liable for medications that are not reasonable/necessary for the palliation and management of the terminal illness and related conditions. Medicare Part D does not cover these types of drugs. These could be medications the patient insists on taking that the hospice interdisciplinary group (IDG) has determined are no longer effective in the intended treatment and/or may be causing additional negative symptoms. These could also be brand name drugs where the patient

refuses to try the generic equivalent that is on the hospice's formulary and there are no medical reasons to indicate that the generic drug cannot/should not be taken. CMS has stated and confirmed that the hospice is not responsible for providing an ABN to the beneficiary in these cases unless the hospice is actually providing the drug to the beneficiary. If the hospice provides the drug even though it is not reasonable and necessary it must provide the ABN in order to charge the patient for the drug. If the hospice does not provide the drug it still must fully inform the beneficiary of his/her liability. If the beneficiary believes Medicare should cover the drug, he/she can submit an appeal directly to Medicare. Appeal information should be provided by the sponsor through the pharmacy at the point of sale (POS).

The Part D Sponsor Pays for the Drug(s)

The Part D plan sponsor pays for the drug when it is completely unrelated to the terminal illness and related conditions only. CMS expects that this will be unusual and occur only in exceptional circumstances. To be clear, CMS is not making it a policy that ALL medications are to be covered by the hospice.

When the Part D plan sponsor receives a claim for drugs in one of the four categories listed above for a hospice beneficiary, the PA process begins. The PA process determines coverage responsibility. The beneficiary, the prescriber or the hospice can provide information regarding this responsibility. Under the new policy, CMS continues to encourage hospices to report a beneficiary's Medicare hospice election to the Part D plan sponsor and identify any drugs in the four categories determined to be covered under Part D prior to the submission of a claim. This advance contact will reduce the likelihood that a patient will have difficulty securing needed medication at POS. CMS is also encouraging use of a standardized two-page form (Hospice Information for Medicare Part D form) on which to communicate this information. All Part D plans should accept the form and the information contained on it, but CMS is not requiring use of the form.

The form streamlines the process with the intent of eliminating delays in hospice beneficiaries receiving medications, but the form is only one component of a streamlined process. According to the memo, many of the delays are the result of the Part D sponsor not having timely notification of a hospice beneficiary's election of hospice care or termination of hospice (discharge or revocation). In order to help in this process CMS guides hospices and Part D plans to take several actions:

- Hospices should submit the NOE (Notice of Election) as soon as possible after the beneficiary elects hospice
- Hospices should submit a final claim as soon as possible after the beneficiary's hospice election is terminated (revocation or discharge) *Note: the first page of the form can be used by the hospice to report only a beneficiary's hospice election or termination (discharge or revocation). There is a checkbox on the form for this purpose.

- The sponsor may accept documentation of a termination from the hospice, the beneficiary, or the prescriber and can accept it in hard copy, mailed or FAXed.
- Acceptable documentation of a termination is as follows:
    - Revocation:
        - Copy of the written statement the patient provides to the hospice indicating the desire to revoke and the effective date of the revocation (i.e. revocation form)
        - Proof of submission of a final hospice claim indicating the date of revocation
    - Discharge for no longer being eligible for hospice care: Copy of the Notice of Medicare Non Coverage (NOMNC)
    - Discharge for cause or transfer out of service area: copy of the hospice discharge summary

      OR
    - Page 1 of the standardized hospice prior authorization form

Because only drugs that are unrelated to the terminal illness and related conditions would be reported on the standardized form, listing the drug here in effect constitutes a statement by the hospice provider or the prescriber that the drug is unrelated. The form provides space for a rationale to support the drug is unrelated; however, no clinical justification for that determination is necessary. To be clear, hospices are no longer required to make a verbal or written statement to the Part D sponsor as to why a medication is unrelated or is not reasonable/necessary. However, hospices are required to have the documentation to support such a decision in the patient's medical record.

In addition to a PA process, the sponsor may have a utilization management (UM) edit. UM edits are drug-specific and their requirements must also be met prior to the hospice beneficiary drug request/claim being fulfilled. CMS indicated that it expects the plan sponsor to concurrently obtain and review the information necessary promptly in order to determine if the UM edit requirement has been satisfied (or, alternatively, whether an exception to that UM requirement has been requested).

There already exists a PA process for Sponsors to follow that is not specifically related to enrollees receiving hospice care. CMS directs Sponsors to follow this same process for hospice beneficiaries. The first step in this process begins when the Part D plan receives a pharmacy claim for a hospice beneficiary for a drug in one of the four categories of drugs subject to the PA process. For all such claims, the Sponsor will reject the claim with the following National Council for Prescription Drug Programs (NCPDP)-approved reject coding:

Reject Code	Description
A3	This product may be covered under Hospice-Medicare A
75	Prior authorization required
569	Provide notice: Medicare Prescription Drug Coverage And Your Rights

Note that these are rejections -- not denials. In addition to the reject coding, CMS stated there should also be a point-of-sale message that the pharmacy receives with the rejection. The wording would be similar to the following: **"Hospice Provider-Request Prior Authorization for Part D Drug Unrelated to the Terminal Illness or Related Conditions".** The message would also include the 24-hour pharmacy help desk phone number to call with questions. NAHC and HAA understand that some Sponsors have created a hospice-specific help desk phone number to call that is staffed by individuals trained in dealing with drugs for Medicare beneficiaries.

How Does the PA Process Work?

If the beneficiary, the beneficiary's appointed representative or the prescriber contacts the Part D sponsor to request a coverage determination for a drug in the four categories, a number of scenarios may occur:

- The sponsor contacts the prescriber to complete the PA. The prescriber may provide a verbal explanation to the sponsor regarding why the drug is unrelated to the terminal illness or related conditions or complete the PA form and submit it to the sponsor via fax or mail.

- In some cases, such as when the prescriber is unaffiliated with the hospice provider and/or is unable or unwilling to coordinate with the hospice provider to supply a statement that the drug is unrelated, the sponsor may contact the hospice for the statement that the drug is unrelated to the terminal illness or related conditions. In these instances, the hospice provider can supply a verbal statement to the sponsor that the drug is unrelated to the terminal illness or related conditions or complete the PA form. CMS believes these instances are most likely to occur when the prescriber is unaffiliated with the hospice provider and may require that the hospice provider contact either the prescriber or the Part D sponsor in order to provide the statement that the drug is unrelated to the terminal illness or related conditions.

    - To ensure care coordination, we believe prescribers who are unaffiliated with the hospice provider, in addition to providing a statement that the drug is unrelated to the terminal illness or related conditions, should also attest that they have coordinated with the

hospice provider and the hospice provider confirmed the unrelatedness of the drug.

- The sponsor contacts the hospice provider to provide the statement of unrelatedness for the PA and is informed that, although the drug is related to the terminal illness or related conditions, it has been determined to be a beneficiary liability.

When the pharmacy receives the claims reject coding with the associated messaging, the *pharmacy contacts the beneficiary or prescriber* to determine if the hospice provider should cover the drug. If the answer is yes, the pharmacy submits the claim to the hospice provider identified by the beneficiary or prescriber. If the answer is no, or neither the beneficiary nor prescriber know whether the hospice provider should cover the drug, the pharmacy will provide the standardized pharmacy notice (i.e., Prescription Drug Coverage and Your Rights - Form CMS - 10147) to the beneficiary and may direct the beneficiary and/or the prescriber to contact the Part D sponsor.

The beneficiary, the beneficiary's appointed representative, or the prescriber must contact the sponsor to initiate the PA fulfillment process. The hospice **cannot** make a determination request on behalf of the beneficiary. This contact is a request for a coverage determination and the sponsor must comply with the coverage determination timeframes and notice requirements. Hospices CAN, however, initiate communication to the Part D plan sponsor prior to a Part D drug claim being submitted and this is expected. For reasons stated previously, CMS and NAHC *encourage hospice providers to initiate communication to the Part D plan sponsor before a request for medications is submitted, ideally when a patient elects hospice.*
Hospice providers can proactively identify a beneficiary's Part D plan through the pharmacy or the beneficiary. Hospice pharmacies can identify a beneficiary's Part D plan by submitting a standard electronic eligibility (E1) query to the CMS Transaction Facilitator. The query response identifies the plan sponsor and provides the sponsor's online billing information, as well as the pharmacy help desk telephone number. The hospice provider can initiate communication or fulfill a PA through the sponsor's 24-hour pharmacy help desk.

The same processing timeframes as those applicable to exception requests are used for adjudicating the claim once the Sponsor has received the explanation for the PA. The timeframes are

- 24 hours for an expedited review
- 72 hours for a standard review

These timeframes begin when the sponsor receives the explanation from the prescriber or hospice. If the sponsor believes it needs additional information, it may request it, which could extend these timeframes, provided, however, that it is not

extended unreasonably. The beneficiary can request an expedited review. NAHC encourages hospices to suggest to all their patients that an expedited review be requested. This is consistent with the life expectancy of a terminally ill individual and for short length of stay hospice patients in particular. CMS expects that the prescriber or hospice respond as quickly as possible to the sponsor's PA request. CMS further expects that the sponsor will accept the response (explanation) from the prescriber or the hospice, either verbally or in writing, and process the claim for payment.

Will There Be Retrospective Determinations of Payment Responsibility?

If the Part D sponsor has paid for drug claims prior to receiving notification of the beneficiary's hospice election, the sponsor must perform a subsequent review of claims paid within the hospice election period and should conduct outreach to the hospice provider or prescriber to make retrospective determinations of payment responsibility for the drugs. In order to determine whether the drug is for treatment of a condition unrelated to the terminal illness or related conditions, CMS expects the prescriber or hospice provider to coordinate with the plan sponsor regarding these claims and, as requested by the sponsor, provide the necessary information explaining why either (1) the drug is unrelated to the terminal illness or related conditions or (2) is a beneficiary liability. The retrospective determination of payment responsibility would only be necessary for claims paid on or after the effective date of the hospice election and prior to the sponsor's receipt of notification that the claim is for a hospice patient. In cases where the Part D plan sponsor has paid for a drug that is the responsibility of the hospice, CMS expects the Part D sponsor and the hospice to negotiate directly with each other. If it is determined that the beneficiary should have paid for the drug, the Part D sponsor may bill the beneficiary for recoupment. The pharmacy is not to be involved in this processing except in cases where the hospice contracted pharmacy is the same as the pharmacy adjudicating the claims. Such would be the case with many nursing facility pharmacies. In these cases, the pharmacy may submit an invoice to the hospice or the beneficiary. Because hospices and the Part D sponsor are to negotiate payment directly with each other the hospice may or may not be able to negotiate a payment rate equivalent to its contracted pharmacy rate.

In its December 6, 2013 memo CMS described an Independent Review Process that could be accessed to make final determinations of relatedness if the sponsor did not agree with the prescriber or hospice that the drug was unrelated. NAHC and many other commenters expressed concern about this process and the qualifications of such a reviewer. CMS stated in the March 10, 2014 memo the Independent Review Process will not be implemented in 2014. It is possible it may be implemented at a future date. Thus, there will be no process for dispute resolution for 2014. Instead, CMS expects:

- The hospice provider and part D sponsor to coordinate their benefits
- The hospice provider or the prescriber to promptly provide verbal communication or written documentation from the hospice provider or

prescriber in order satisfy the beneficiary-level PA. That is, information explaining the drug is unrelated to the terminal illness or related conditions, or is related to the terminal illness or related conditions and, therefore, is a responsibility of the hospice provider or beneficiary;
- The Part D sponsor to accept and maintain the documentation that the drug is unrelated to the terminal illness or related conditions and is, therefore, reimbursable under D and process the claim; and
- The sponsor and hospice to negotiate the retrospective recovery of the amounts paid, if the sponsor has paid for drugs after the effective date of the hospice election, but prior to receipt of notification from CMS.

As previously stated, in order to minimize any wait times for hospice patients submitting drugs for Part D payment, the hospice should submit the Notice of Election (NOE) for hospice care as soon as possible after it is completed. This notifies CMS that the patient is now receiving hospice care and the Part D plan sponsors will be able to find this information as well as the name and contact information for the hospice in the system. CMS indicates the hospice contact information will be available electronically in the HPMS (Health Plan Management System) and on the cms.gov website prior to May 1. The information that will be here is from the PECOS system so CMS encourages hospice providers to verify that their contact information is up to date so it will be correct when posted to the website.

There were several attachments to the March 10, 2014 memo that are quite useful for hospices. They may even wish to share these with patients. These are:
- Attachment 1 – Prior Authorization based on Part D Claim Reject at Point-of-Sale (a diagram of the PA process)
- Attachment 3 – Hospice Data Flow

Additional information and tips for implementation can be found in the NAHC Hospice and Part D Tips document.