

MLN Matters Number: SE0626

Related Change Request (CR) #: N/A

Related CR Release Date: N/A

Effective Date: N/A

Related CR Transmittal #: N/A

Implementation Date: N/A

**Note:** This article was updated on October 1, 2012, to reflect current Web addresses. All other information remains unchanged.

## Coverage of Prescription Niacin Products Under Part D for 2006

### Provider Types Affected

Physicians and other providers who prescribe medications for Medicare patients under Medicare Part D

### Key Points

- On April 11, 2006, the Centers for Medicare & Medicaid Services (CMS) informed Medicare Part D prescription drug coverage plans, via a memorandum titled “**CMS Clarification of Coverage of Prescription Niacin Under Part D,**” that was issued over the Health Plan Management System (HPMS), that prescription Niacin products (Niaspan®, Niacor®) can be a covered Part D drug for treatment of dyslipidemic therapy and may be included on Medicare prescription drug plan formularies. Medicare prescription drug plans have the option of covering those drugs immediately.
- For the remainder of contract year 2006, Medicare Part D plans may put prescription Niacin products (Niaspan®, Niacor®) on their formularies, but they are not required to do so. As a result, enrollees may obtain coverage of prescription Niacin products either as a formulary drug or as a non-formulary drug through the exceptions process.
- For contract year 2007, prescription Niacin products (e.g., Niaspan® and Niacor®) used at dosages much higher than appropriate for nutritional supplementation should be considered for formulary inclusion similar to all other Medicare Part D drugs.
- Please refer to the *Additional Information* section of this Special Edition article for specific information regarding two methods for Part D Medicare beneficiary enrollees to obtain prescription Niacin products for the remainder of 2006

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

## Background

---

The prescription Niacin products are used therapeutically for the treatment of dyslipidemia at much higher dosages than are appropriate for nutritional supplementation. They do not serve as a nutritional supplement or to address a vitamin deficiency. For these reasons, CMS has decided that prescription Niacin products should not be considered a prescription vitamin for purposes of Medicare Part D coverage.

Prescription Niacin products are not universally excluded from coverage under the Medicare prescription drug program. This reverses an earlier February 3, 2006 decision by CMS that prescription Niacin products (Niaspan®, Niacor®) are prescription vitamins and therefore are excluded from the definition of a Medicare Part D drug under the statute.

## Additional Information

---

### *Prescribing Prescription Niacin products (Niaspan®, Niacor®) for the Remainder of 2006*

For Medicare beneficiaries in plans that INCLUDE prescription Niacin products on their formulary:

- If prescription Niacin products **are not subject** to prior authorization – a Medicare prescriber writes a prescription for the prescription Niacin product and the Part D enrollee has the prescription filled at a local retail pharmacy or a mail order pharmacy. If the enrollee is a resident of a long term care facility, the prescription will be filled by the long term care pharmacy serving that facility.
- If prescription Niacin products **are subject** to prior authorization—the Medicare prescriber must file a prior authorization request on behalf of the enrollee. Each Medicare Part D plan has its own form, available on the plans' web sites (some plans have specific forms for particular drugs; others use a standard prior authorization form).
- Plans must approve or inform the enrollee why they have disapproved a prior authorization request within 72 hours. An enrollee or an enrollee's physician can request an "expedited coverage determination" for a decision within 24 hours if the enrollee's health, life, or ability to regain maximum function may be seriously jeopardized by waiting 72 hours for a decision.
- If a Medicare Part D plan disapproves a prior authorization request (i.e., makes an "adverse coverage determination"), the enrollee has the right to request a redetermination from the plan sponsor (see below).

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

For plans that **do not** have prescription Niacin products (Niaspan<sup>®</sup>, Niacor<sup>®</sup>) on their formularies:

- If a Medicare beneficiary is currently taking a prescription Niacin product and is enrolled in a Medicare Part D plan that does not include prescription Niacin products on its formulary, the beneficiary can now ask for an exception to get coverage for a prescription Niacin product (see below).
- If a Medicare beneficiary who is currently taking a prescription Niacin product enrolls in a Medicare Part D plan that does not include prescription Niacin products on its formulary, the plan is required to have a process to ensure the enrollee's smooth transition into the plan and to allow the enrollee time to obtain medically necessary exceptions to the plan's formulary.
- Many Medicare Part D plans have adopted a "first fill" policy that will allow enrollees to have their first prescription for the prescription Niacin product filled even if prescription Niacin product are not on the plan's formulary. This will allow Medicare beneficiaries who have been stabilized on a prescription Niacin product to continue taking it while they request exceptions.
- The transition process is a very temporary solution, however, and enrollees and providers should not delay pursuing exceptions. Prescribers may advise enrollees to contact their plans for more information about their plan's transition process.

### *Exceptions and Appeals*

If a physician prescribes a non-formulary drug for an enrollee, the enrollee or physician must request an exception, which is a type of coverage determination, to obtain the non-formulary drug for the enrollee. If the plan sponsor's coverage determination is unfavorable, the enrollee may appeal the plan sponsor's decision.

### **Exceptions**

An enrollee or an enrollee's physician has the right to request an **exception** for coverage of non-formulary prescription Niacin products. The enrollee's prescribing physician should submit a statement supporting the exception request. The Part D plan must notify the enrollee of its decision within 72 hours after receiving the physician's supporting statement. If the enrollee or physician requests an expedited decision, the plan sponsor must notify the enrollee of its decision within 24 hours after receiving the physician's supporting statement if the plan determines, or the enrollee's physician indicates, that applying the 72-hour timeframe may seriously jeopardize the enrollee's life, health, or ability to regain maximum function.

The plan must grant the exception if it determines that the requested drug is medically necessary, consistent with the physician's statement. The Medicare provider physician's statement must state that the exception is medically

#### **Disclaimer**

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

necessary to treat the Medicare beneficiary enrollee's disease or medical condition because all of the covered Medicare Part D drugs on any tier of the plan's formulary for treatment of the same condition would not be as effective as prescription Niacin products, would have adverse effects, or both.

### Appeals

If a plan sponsor issues an adverse coverage determination, the decision may be appealed. There are five successive levels of appeal.

- If a plan sponsor issues an unfavorable coverage determination, the enrollee has the right to request a standard or expedited **redetermination** with the plan sponsor within 60 calendar days from the date of the notice of the plan sponsor's adverse coverage determination. Enrollees or their prescribing physician can submit written evidence and legal arguments for coverage of prescription Niacin products during the redetermination process. The plan sponsor must notify the enrollee of its decision within 7 calendar days after receiving a standard request, or 72 hours after receiving an expedited request.
- If the plan sponsor's redetermination decision is unfavorable, the enrollee has the right to request **reconsideration** by the independent review entity (IRE) that contracts with CMS. This request must be submitted in writing within 60 calendar days from the date of the notice of the plan sponsor's adverse redetermination decision. The IRE must solicit the views of the prescribing physician orally or in writing and must notify the enrollee of its decision within 7 calendar days after receiving a standard request, or 72 hours after receiving an expedited request.
- If the IRE denies the request for coverage and the amount remaining in controversy is at least \$110, the Medicare beneficiary enrollee has the right to request a **hearing before an Administrative Law Judge (ALJ)**. The request must be filed in writing within 60 calendar days from the date of the notice of the IRE's adverse reconsideration determination.
- If the ALJ's decision is unfavorable, the enrollee has the right to request a review by the **Medicare Appeals Council**. The request must be filed in writing within 60 calendar days from the date of the notice of the ALJ's adverse decision.
- If the MAC issues an adverse decision, the enrollee has the right to request judicial review of the ALJ's decision by **filing a civil action in U.S. District Court** if the amount remaining in controversy is at least \$1,090. The request must be filed in writing within 60 calendar days from the date of the notice of the MAC's adverse decision.

For additional information, CMS has a number of MLN Matters special edition articles on the new drug program, especially the fourth and fifth articles in the MLN Matters series about Medicare's new prescription drug coverage.

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.

SE0537, *New Educational Products Available*, is the fourth article in the series and can be found at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/SE0537.pdf> on the CMS website.

SE0541, *More Web-based Educational Products Available on Medicare Prescription Drug Coverage*, is the fifth article in the series. It is available at <http://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnmattersarticles/downloads/SE0541.pdf> on the CMS website.

#### Disclaimer

This article was prepared as a service to the public and is not intended to grant rights or impose obligations. This article may contain references or links to statutes, regulations, or other policy materials. The information provided is only intended to be a general summary. It is not intended to take the place of either the written law or regulations. We encourage readers to review the specific statutes, regulations and other interpretive materials for a full and accurate statement of their contents.