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CMS Expands Off-Label Prescription Drug Use for Cancer Treatment

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CMS recently issued an interim final rule that expands Medicare coverage for certain off-label uses of drugs in anticancer chemotherapy regimens. The new rule expands the sources available to determine a medically accepted use, and allows Part D plans limited discretion to cover additional uses.

Pursuant to the Medicare Improvements for Patients and Providers Act (MIPPA), the new rule expands the list of approved compendia that may be used to determine "medically accepted indications" of drugs, as that term is applied to Part D drugs used in anticancer chemotherapy regimens. The new rule also offers a Part D plan discretion to cover additional off-label use if scientific literature approved by the Secretary of Health and Human Services (Secretary) supports such use.

For Part D drugs not utilized in anticancer chemotherapy regimens, MIPPA retains the existing definition of "medically accepted use," which can be found in the Medicaid rebate statute. However, MIPPA requires the Secretary to update the list of compendia used under the existing definition to determine a medically accepted use.

The interim final rule may be viewed [here](#).

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