

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland



CENTER FOR MEDICARE

October 23, 2024

Warning Letter

Contract ID: S7126

Formulary ID(s): 24205, 24214, 24218

Parent Organization Name: Mutual of Omaha Insurance Company

Legal Entity Name: OMAHA HEALTH INSURANCE COMPANY

Lisa Artale Bross
Medicare Compliance Officer
3300 Mutual of Omaha Plaza
Omaha, NE 68175

VIA EMAIL: Lisa.ArtaleBross@mutualofomaha.com

RE: FAILURE TO ADD PROTECTED CLASS DRUG(S)

Dear Lisa Artale Bross:

The Centers for Medicare & Medicaid Services (CMS) is issuing this warning letter to OMAHA HEALTH INSURANCE COMPANY, which operates Medicare Part D plan S7126. Your organization is out of compliance with CMS's Part D program requirements regarding formulary updates involving prescription drugs that meet the criteria for placement among the following protected classes: immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic. We are issuing a warning letter because CMS previously issued a notice of non-compliance to your organization for missing protected class drug(s) during the August 2024 formulary file submission window.

Consistent with 42 C.F.R. § 423.120(b)(2)(v), Part D sponsors must include in their formularies all drugs within the six classes of clinical concern identified by CMS. [1] Pursuant to instructions in the Medicare Prescription Drug Benefit Manual, Chapter 6, Part D Drugs and Formulary Requirements, Section 30.2.5, "New drugs or newly approved uses for drugs within the [protected] six classes that come onto the market after the CMS specified formulary upload date will be subject to an expedited [pharmacy and therapeutics] P&T committee review. The expedited review process requires sponsors' P&T committees to make a decision within 90 days of when the drug is released onto the market, rather than the normal 180-day requirement. At the end of the 90-day period, these drugs must be added to Part D plan formularies." Then, the drugs must be included on the sponsor's Health Plan Management System formulary file during the next available submission window.

CMS is issuing this compliance notice to your organization because it had missing protected class drug(s) during the September 2024 formulary file submission window. The specific protected class issue was as follows:

The sponsor was missing protected class drugs during the September 2024 submission window. TOVORAFENIB oral suspension and TOVORAFENIB tablets became market available 05/06/2024. 90 days after launch was 08/04/2024. The sponsor should have added the protected class drugs by the September submission window to maintain substantially all protected class drugs on its formulary.

Please be aware that this letter will be included in the record of your organization's past Medicare contract performance, which CMS will consider as part of our review of any application for new or expanded Medicare contracts your organization may submit. CMS deems this instance of non-compliance a Part D issue. CMS notes that we are issuing this compliance notice based exclusively on information that we obtained from sources other than the sponsor's own self-disclosure.

In the future, please ensure that your organization's formulary is updated and approved within CMS's specified timeframe. If you have questions regarding your formulary updates please contact the Part D Formulary mailbox at PartDformularies@cms.hhs.gov. If you have any questions regarding the compliance implications of this notice, please contact Christine Hill at Christine.Hill@cms.hhs.gov and copy your account manager.

Sincerely,



Linda Anders, Division Director
Division of Benefit Purchasing and Monitoring
Medicare Drug Benefit and C&D Data Group

CC via email:

Cynthia Ford, CMS
Arianne Spaccarelli, CMS
Brian Martin, CMS
Christine Hill, CMS

[1] These six classes, as identified in the previous paragraph, were spelled out in the Patient Protection and Affordable Care Act, Pub. L. 111-148, 124 Stat. 119 (March 23, 2010). A copy of this Act can be found at <https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf>. These protected classes can also be found at 42 U.S. Code § 1395w-104(b)(3)(G)(iv).