

## 10.2 - Covered Part D Drug

*(Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)*

A covered Part D drug is a Part D drug that is included in a Part D sponsor's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under 42 CFR §§[423.566](#), [423.580](#), *and* [423.600](#), and obtained at a network pharmacy or an out-of-network pharmacy in accordance with 42 CFR [§423.124](#). *For the applicable drugs of a manufacturer to be covered under Part D, the manufacturer must participate in the Medicare Coverage Gap Discount Program. An applicable drug is a Part D drug that is approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or a biologics license application under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such Act). Thus the definition of applicable drugs excludes biological products approved under the abbreviated licensure pathway (biosimilars).*