ACCESS TO COMBINATION THERAPIES IN EXCHANGE PLANS

Combination therapies are medications that contain two or more pharmaceutical ingredients in a single dosage form (e.g., tablet, capsule) for the treatment of a condition. Oftentimes, patients living with chronic conditions—such as HIV and diabetes—rely on combination therapies because they reduce the number of medications or dosages a patient must take, which can increase adherence and clinical efficacy.

An analysis of silver exchange plans examined coverage of single-source combination and single-ingredient products in specified medication classes to better understand access to combination therapies in exchange plans.[1]

ACCESS TO COMBINATION MEDICINES

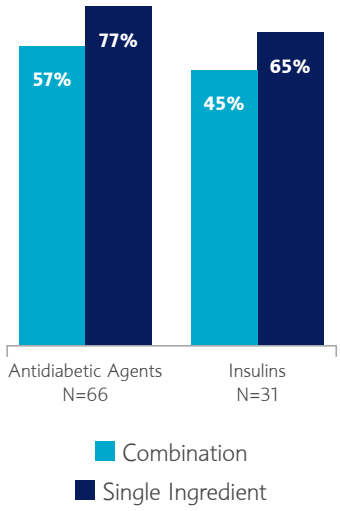
Exchange plans are less likely to cover combination medicines than other brand HIV/AIDS and diabetes medicines.

Under the current essential health benefits (EHB) rules governing coverage of medicines under the Affordable Care Act (ACA) combination medicines generally do not count towards meeting the EHB standards if the individual component medicines are covered by a plan. This reduces the incentive for exchange plans to cover these combination medicines, particularly if such combinations are more expensive than the individual ingredients purchased separately.

The drug counting methodology that was used in 2014 and will again be used in 2015 requires plans to meet state-specified counts of unique chemical entities in each medication class. Since combination medicines have more than one chemical entity, they are typically not "unique" and do not, therefore, help exchange plans meet the required standard.

In exchange plans, combination antidiabetic agents and insulins are covered substantially less frequently than single-ingredient medications in the same drug classes. Combination antidiabetic agents are covered 26% less often than single-ingredient therapies, and combination insulins are covered 30% less often than single-ingredient medicines. Across both classes, diabetes single-ingredient therapies are covered 70% of the time, while combination therapies are covered only 50% of the time.

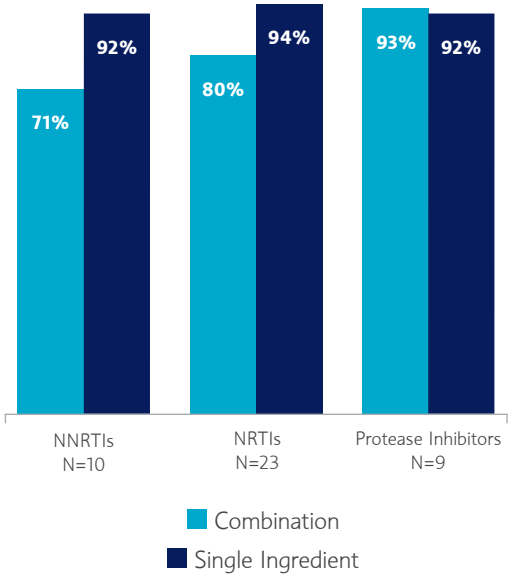
Coverage of Combination vs. Single Ingredient Diabetes Therapies



Analytics by Avalere Health. Developed by PhRMA.

Similarly, HIV/AIDS combination therapies, particularly those that include NNRTIs and NRTIs[2], are covered at lower rates than single-ingredient medications in exchange plans.[3] Combination NNRTIs are covered 23% less often than single-ingredient NNRTIs, and combination NRTIs are covered 15% less often than single-ingredient NRTIs. Across three classes of HIV/AIDS medications, HIV single-ingredient therapies are covered 92% of the time, while combination therapies are covered only 82% of the time in exchange plans.

Coverage of Combination vs. Single Ingredient HIV/AIDS Therapies



LACK OF COVERAGE FOR COMBINATION MEDICINES HARMS EXCHANGE PATIENTS

The current counting methodology fails to take into account coverage of combination therapies. This policy may contribute to plans covering combination therapies at lower rates than their single-ingredient counterparts in diabetes and HIV/AIDS classes. Patients with chronic conditions requiring treatment using combination therapies could find limited access to their needed medications among exchange plans.

Combination therapies for HIV/AIDS and diabetes reduce pill burden on patients by lowering dosing frequency and supporting medication adherence and clinical efficacy. Researchers have described combination HIV medicines as representing "a significant advance in the simplification of antiretroviral therapy, facilitating adherence to complex and chronic treatments, and contributing to a quantifiable improvement in patient quality of life."[4] Additionally, an American and European task force convened to develop type 2 diabetes care recommendations and generally recommended the use of combination therapy when initial drug monotherapy does not achieve adequate outcomes. The recommendations further state that for several two-drug combinations there is high clinical efficacy associated with use.[5]

LOOKING AHEAD

The drug counting methodology was intended to be a mechanism to ensure adequate drug coverage in exchange plans. This approach allows health plans great flexibility to design coverage, but has resulted in limited patient access to certain medications. In particular, the current counting methodology largely ignores combination medicines, in effect, discouraging exchange plans from covering these therapies.

The current EHB regulation was originally intended to govern coverage in 2014 and 2015. The Centers for Medicare & Medicaid Services has not indicated whether they are working to update the EHB rules. However, such an update is needed and should take this data on combination medicines into account. Revisions to the EHB rules related to prescription medicines should ensure that exchange plans reflect advancements in care and are not discouraged from covering combination medicines.

[1] Analysis by Avalere Health. Avalere analyzed a database of 108 silver exchange plan formularies that span 50 states and DC. Avalere reviewed coverage statistics (including statistics regarding utilization management and drugs that have no data available) for single-source (defined as medicines for which a generic equivalent is not available) combination and single-source single ingredient products in the specified classes of medications.

[2] NNRTI = Non-nucleoside Reverse Transcriptase Inhibitors and NRTI = Nucleoside and Nucleotide Reverse Transcriptase Inhibitors

[3] Results for combination therapies by class include all combination medicines that have a molecule in a particular class.

[4] J.M. Llibre, et al. "Clinical implications of fixed-dose combinations of antiretrovirals on the outcome of HIV-1 therapy." AIDS, 25(14): 1683–1690, 10 September 2011.

[5] *Diabetologia*, Position Statement, "Management of hyperglycaemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD)", February 2012, accessed via: http://link.springer.com/article/10.1007/s00125-012-2534-0#page-1