

## CAN A POSITIVE COMPENDIA LISTING SUPPORT OFF-LABEL COVERAGE AND REIMBURSEMENT?



# Using published evidence and compendia to support coverage for an off-label medication dosage

A pharma company asked Magnolia to evaluate the likelihood that a drug compendia would support an off-label dose for a drug with an FDA-approved maximum dose.

Payers look to compendia evaluations to deem certain off-label uses of drugs clinically appropriate, and use them to support coverage and reimbursement.

Published clinical data showed some patients benefited from an increased dose, and tolerability was not affected at higher doses. However, small data sets in this orphan disease state made subsequent FDA approval of higher dosing impractical.



### What payers look for in supporting off-label use

**Government payers will consider off-label coverage** if supported by one of the Medicare-accepted compendia, when not directly contradicted by another. FDA drug approval, even if for a different indication, is also given weight.

**Commercial payers showed greater variability.** While both government and commercial payers accommodate off-label data published in peer-reviewed medical journals and compendia, commercial payers may choose not to use a positive compendia listing as a basis for coverage.



### Picking the right compendia

**Magnolia reviewed all compendia listings** for the drug and identified which drug compendia offered the best opportunity to secure a positive rating and avoid the coverage implications of negative valuation.

**One compendium accepted lower levels of evidence** (eg, phase 2 studies) in rare diseases and had previously approved comparator products with dosing limitations that had similar published clinical evidence.



### Client Outcomes

**Magnolia recommended** that the pharma company submit high-dose use data to the identified compendium.

**Magnolia partnered** with the pharma company to build a data packet for compendium submission. This data packet included clinical studies supporting tolerability at the higher, off-label dose. Upon favorable compendium listing of this product, the client was able to secure payer coverage for off-label, higher-dose use with federal programs and several key commercial payers.