

# Do US managed care organizations restrict coverage more than the Food and Drug Administration label?

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## Introduction

Medical policies (MPs) are developed by US payers to assist the administration of health benefits, particularly where there are multiple treatment options for a specific indication. The most widely known mechanisms used by US payers to determine appropriateness of coverage through utilization management include step therapy (ST), prior authorization (PA), and quantity limits (QL). There is a need to understand how these management strategies compare with the Food and Drug Administration (FDA) label. Our goal is to determine whether managed care organizations (MCOs; a type of payer) tighten health plan management of drugs compared with the FDA label.

## Methods

- Secondary research identified MPs for six drugs in three therapy areas (spinal muscular atrophy [SMA], psoriasis, and systemic lupus erythematosus [SLE]).
- Two therapies were explored in each therapy area: Spinraza® and Zolgensma® in SMA; Sotyktu® and Otezla® in psoriasis; and Benlysta® and Saphnelo® in SLE.
- We reviewed 18 covered determinations (CDs), one for each drug, from three MCOs (United Healthcare, Anthem Blue Cross Blue Shield, and Aetna).
- Definitions: “More restrictive” was defined as coverage requiring elements beyond what is defined in the FDA label such as later lines of therapy, requiring more and different previous therapy, patient identification criteria that restrict access to a smaller population, and burdensome tests or paperwork. “At label” was defined as coverage aligned to the FDA indication patient population. “Less restrictive” was defined as coverage access broader than the FDA indication.

## Results

### SMA treatment findings

- All MCO coverage policies reviewed were more restrictive than the FDA label for both Spinraza®, which has a broad indication for the treatment of SMA in pediatric and adult populations, and Zolgensma®, which has a narrower indication for the treatment of SMA in patients less than 2 years of age with mutations in the survival motor neuron 1 (SMN1) gene. Some of the restrictive elements seen across MCOs included submission of medical records confirming mutation/deletion of genes and baseline motor ability, no advanced disease such as dependence on invasive ventilation or tracheostomy, specialist healthcare professional requirements, and no concomitant motor neuron modifying therapy.
- While United Healthcare (UHC) is the only insurer not requiring PA for Spinraza®, all placed a QL on Spinraza® for 12 months while there is no stopping rule in the label. UHC did not allow previous treatment with Zolgensma®, but Anthem and Aetna did allow previous treatment.
- All MCOs require PA before the initiation of Zolgensma®. However, there were no QLs by any payer for Zolgensma®. UHC requires prophylactic glucocorticoid treatment while the others do not. UHC and Anthem do not include full paralysis in their definition of advanced disease, while Aetna will disqualify based on full paralysis.
- None of the three MCOs required ST prior to initiating Spinraza® or Zolgensma®.

### Plaque psoriasis treatment findings

- MCOs require not only PAs but have also implemented QL for both Otezla® and Sotyktu®.
- UHC covers Otezla according to the FDA indication, with no additional requirements, whereas a prior authorization form for Anthem requires previous treatment failure with a topical steroid and Aetna requires multiple ST and treatment failures including biologic, phototherapy or topical treatment, and methotrexate, cyclosporine, or acitretin. The QL for all MCOs is a specific dispensing limit to a one-month supply per prescription.
- UHC requires “medical necessity” for Sotyktu, including documentation of the percentage of body surface involvement and details around multiple treatment failures, which is similar to Anthem which considers Sotyktu as “non-formulary,” but an override is possible. On the other hand, Aetna covers Sotyktu as “indication-based coverage,” and is a preferred specialty product. Information was not found on PA, QL, or ST requirements.

### SLE treatment findings

- Benlysta® and Saphnelo® face varying levels of coverage restrictions across these MCOs, with Anthem generally imposing more stringent criteria than UHC and Aetna for both treatments. PAs were requested by all MCOs, and QL and ST implemented by UHC and Anthem.
- Benlysta® is considered proven and medically necessary and covered at label by UHC, but is more restricted by Anthem (requiring disease activity documentation both scoring and antibodies, and current treatment failure) and Aetna (only disease activity by antibodies). Initial approval QL is 12 months for UHC but 6 months for Anthem.
- UHC will cover Saphnelo® at label, but for medical necessity, restrictions are implemented including failure of Benlysta, while Anthem requires ST failure of Benlysta® before the use of Saphnelo®. Anthem and Aetna require documentation of disease activity.

Table 1: Payer archetypes and data sources used to inform coverage determinations

	SMA		Plaque psoriasis		SLE	
	Spinraza <sup>1</sup>	Zolgensma <sup>2</sup>	Otezla <sup>3</sup>	Sotyktu <sup>4</sup>	Benlysta <sup>5</sup>	Saphnelo <sup>6</sup>
United Healthcare	More restrictive than label <sup>c</sup> QL <sup>7</sup>	More restrictive than label <sup>c</sup> PA <sup>11</sup>	At label PA, QL <sup>14-16</sup>	More restrictive than label <sup>b</sup> PA, QL, ST <sup>24-25</sup>	At label PA, QL <sup>29-31</sup>	More restrictive than label <sup>a</sup> PA, QL, ST <sup>34</sup>
Anthem	More restrictive than label <sup>a</sup> PA, QL <sup>8</sup>	More restrictive than label <sup>b</sup> PA <sup>12</sup>	More restrictive than label <sup>a</sup> PA, QL, ST <sup>17,18</sup>	More restrictive than label <sup>b</sup> PA, QL, ST <sup>26-27</sup>	More restrictive than label <sup>b</sup> PA, QL, ST <sup>32</sup>	More restrictive than label <sup>b</sup> PA, QL, ST <sup>35</sup>
Aetna	More restrictive than label <sup>a</sup> PA, QL <sup>9-10</sup>	More restrictive than label <sup>b</sup> PA <sup>13</sup>	More restrictive than label <sup>b</sup> PA, QL <sup>19-23</sup>	At label <sup>28</sup>	More restrictive than label <sup>a</sup> PA <sup>33</sup>	More restrictive than label <sup>a</sup> PA <sup>36</sup>

<sup>a</sup><5 additional criteria not spelled out in the FDA indication or label;  
<sup>b</sup>5-9 additional criteria not spelled out in the FDA indication or label;  
<sup>c</sup>≥10 additional criteria not spelled out in the FDA indication or label.

## Conclusions

Variations were seen in the three MCO coverage policies and their restrictions. Across all indications, Anthem seems to have implemented more restrictions to manage treatments in SMA, psoriasis, and SLE. This can impact patient access to effective treatments in the disease areas explored. The use of PA and QL specifically has been common among the three MCOs reviewed; these MCOs also tend to restrict more than the FDA label. These methods of management help to both manage how certain medications are used among their member's plans. This may be done to control the drug costs for high-cost medications when less expensive alternatives that may be equally effective are also available and easily accessible to patients. The use of clinical evidence during utilization management may also influence these payer decisions. Proper strategies should be implemented by manufacturers to identify which of their treatments may fall under these types of management. Specific coverage details will vary with each member's plan. There is a further need to explore the cost factors and potential barriers for other payer archetypes. Additional clarity is needed in terms of what clinical evidence material is reviewed by MCOs prior to deciding the utilization management strategies.

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