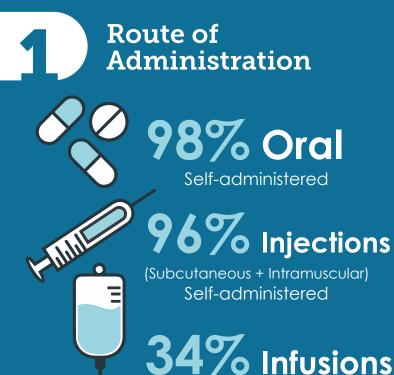
## Multiple Sclerosis Drugs Market Insights

Disease modifying drugs for the treatment of multiple sclerosis (MS) is a crowded, dynamic therapeutic class. Payers give preference to at least one drug from each of the major MS drug classes, often older drugs and generics, leaving limited opportunities for proprietary and newer MS drugs.

## **Preferred Formulary Status by**



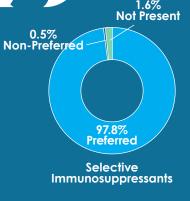
Provider administered infusion drugs are often covered under the medical rather than pharmacy benefit, which accounts for the low number of preferred infusion drugs. Three out of the four monoclonal antibodies (Lemtrada, Ocrevus, Tysabri) are provider administered, so this drug class is underrepresented in the formulary data set.

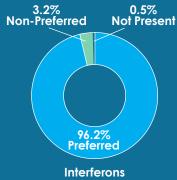
Provider administered

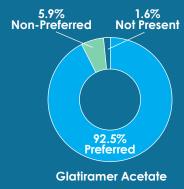
#### Number of Covered Lives (mn)

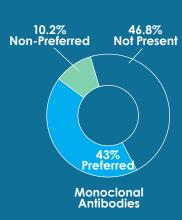
Betaseron (93.4) dimethyl fumarate (81.6) Glatiramer acetate (79.9) Rebif (78.7) **Glatopa** (78.3) Avonex (68.9) **Gilenya** (67.8) Pharmacy Benefit **Aubagio (53.9) Mayzent (48.8)** Copaxone (46.4) Plegridy (33.9) Zeposia (30.3) Kesimpta (28.8) **Extavia** (26.2) Mavenclad (23.8) Vumerity (22.9) Tecfidera (21.8) Tysabri (19.7) Lemtrada (14.4) Ocrevus (9.7)

# Drug Class



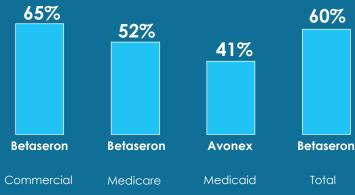






# Line of Business

**Most Preferred Drug agents** 



Tecfidera's frequent non-preferred status is likely associated with the recent expiration of its patent and the subsequent release of generic dimethyl fumarate.

#### **Least Preferred Drug agents**



6.5%

Commercial

Zeposia. Mavenclad Medicare

**Tecfidera** 

16.3%

Medicaid

Tecfidera

Total

### **Average Number of Preferred Drugs** Per Formulary Document

Commercial (9)

Managed Medicaid (7)

Medicare Advantage (8)

**Medicare Part D (10)** 

All Line of Business (9)

Interferon (3)

glatiramer acetate (2)

Selective Immunosuppressants (3)

**Monoclonal Antibodies (1)** 



15% of United Healthcare formularies and 8% from Anthem do not prefer glatiramer acetate, one of the most extensively utilized injectable agents, which has two generics available.

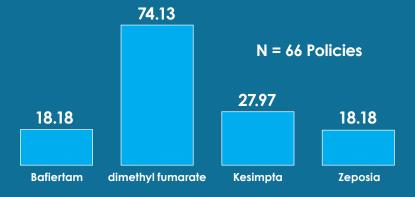
ANTHEM

<sup>&</sup>quot;Not present" when the drug is not named on the formulary document.

<sup>&</sup>quot;Preferred" refers to when the drug is named as a "preferred" drug on the formulary document. Preferred drugs are lower tier than non-preferred drugs. "Non-preferred" refers to when the drug is named as a "non-preferred" drug on the formulary document.

This section pulls data directly from high importance policy alerts (a component of PolicyCore subscription) to provide an overview of changes that took place in Q1 of 2021 across all payers

The highly dynamic market is demonstrated by percentage of policies with a newly released MS brand or generic drug tracked by Policy Reporter in Q1 2021



The introduction of generics to any disease modifying MS drug is likely to generate many policy changes to take advantage of generic pricing opportunities. Even if the introduction of a new drug does not alter the position of preferred drugs, many payers will update their documents to show the coverage position of a new drug.

#### High Importance Changes to MS Drug Policies in Q1 2021

Changes to coverage criteria or step therapy account for the majority of high importance changes (such as changes to applicable drugs, criteria, step therapy, coding, and/or lines of business) tracked by Policy Reporter. Across all updated policies, criteria changes make up slightly more than half of all high importance changes. Commercial policies follow this trend, but criteria changes make up two thirds of all high importance changes to Medicaid policies for MS drugs. This difference may be due to Medicaid state-specific requirements.



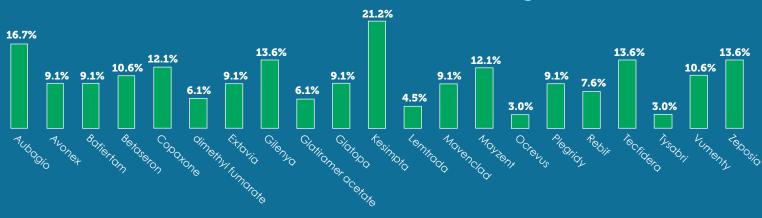
- NEW BRAND ADDED
- **150** GENERIC ADDED
- COVERAGE CRITERIA / STEP THERAPY CHANGE
- 47 NEW POLICY
- 49 NEW BRAND ADDED
- **70** GENERIC ADDED
- COVERAGE CRITERIA / STEP THERAPY CHANGE

- **304** MEDICAID
- 14 NEW POLICY
  - 15 NEW BRAND ADDED **71** GENERIC ADDED
  - COVERAGE CRITERIA STEP THERAPY CHANGE
- **NEW POLICY NEW BRAND ADDED 60**

361

- GENERIC ADDED
  - COVERAGE CRITERIA STEP THERAPY CHANGE

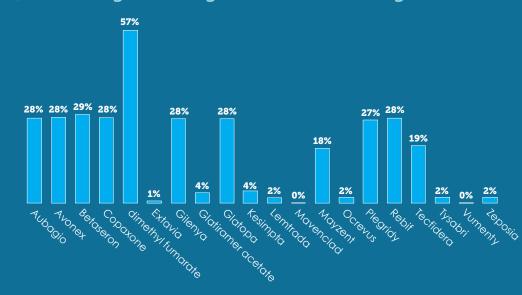
#### Percentage of New Policies Introduced in Q1 2021 That Address the Given Drug



Most new policies apply to a single drug, but some multi-drug policies for all MS agents are also released. Payers released more new policies addressing Kesimpta than for any other MS drug in Q1, unsurprising as Kesimpta is one of the latest entrants to the market.

#### Criteria Changes: Drugs That Were Added or Removed to/from the Criteria Set, Affecting Coverage of Another Drug

More than twice as many step therapy changes involved generic dimethyl fumarate compared to any other MS drug. These changes frequently included the addition of a dimethyl fumarate step or replacing Tecfidera with dimethyl fumarate in step therapy requirements. This is consistent with trends observed in formulary coverage, where dimethyl fumarate is the second most preferred MS agent by covered lives and Tecfidera is the least preferred pharmacy benefit MS agent by covered lives.



### **Formulary**

#### Publication Parameters













Number of formularies analyzed









#### **Policy Alerts**



Kesimpta, Lemtrada, Ocrevus, Tysabri















Drug Class	Drugs
nterferons	Avonex, Betaseron, Extavia, Plegridy
Glatiramer Acetate	Copaxone, Glatiramer acetate, Glato
Selective	Aubagio, dimethyl fumarate, Gilenya

Mode of Administration	Drugs
Oral (self administered)	Aubagio, Mavenclad, Gilenya, Mayzent, Zeposia, dimethyl fumarate, Tecfidera, Vumerity
Subcutaneous and Intramuscular Injections (self administered)	Avonex, Plegridy, Rebif, Betaseron, Extavia, Copaxone, Glatiramer acetate, Glatopa, Kesimpta
Infusions (provider administered)	Lemtrada, Ocrevus, Tysabri

Monoclonal Antibodies

- "Policy alerts (Update notes)" are emails that alert Policy Reporter clients of changes when a payer revises a document or releases a new document
- "Updates" occur when Policy Reporter tracks a change to a document. Our Healthcare Document Analysts write alerts (update notes) to notify our customers of these changes. "High importance updates" include changes to coverage criteria, step therapy, applicable drugs, coding, and/or applicable lines of business, or when a new document is released.
- "New brand added" indicates that a brand name drug which launched in Q2 2020 or later (Bafiertam, Kesimpta, Zeposia) was added to the document. Bafiertam is included in the update notes data set but was not included in theformularies data set.
- "Coverage criteria or step therapy change" indicates that requirements for coverage changed for at least one drug mentioned in the policy. Criteria may have become more

"New generic added" indicates that a generic version of a drug that went off patent in Q2 2020 or later (dimethyl fumarate [generic Tecfidera]) was added to the document.

- "Coverage criteria or step therapy change involving a new brand or generic" is a subset of the documents with coverage criteria or step therapy changes, in which the changes specifically include drugs launched in Q2 2020 orlater (Bafiertam, generic dimethyl fumarate, Kesimpta, Zeposia). "New policy" indicates that a new document was published by the payer, rather than a new version (update) of an existing policy. Often this is because the payer had no previous coverage position for the drug(s), though a newpolicy may also be added for a specific line of business.