MMIT RADAR

Radar on Market Access

Actionable understandings from AIS Health's in-depth coverage

January 2019

MMIT Updated 2019 Brand Market Access Data for 83% of Lives by Jan. 15

Most pharmacy benefit plans change formularies each year in January. Knowing that pharmaceutical and payer customers rely on an accurate view of lives and coverage data as early in the new plan year as possible, MMIT has made updating 2019 market access data a key priority. By Jan. 9, MMIT had updated formulary data for 100% of Medicare lives and 73% of non-Medicare lives, rising to 83% by Jan. 15.

MMIT data will be updated to reflect 2019 formulary coverage for 98% of total U.S. lives by the end of January. It has the most comprehensive 2019 coverage data in the industry — and completes lives updates more rapidly each year.

By comparison, in 2018, MMIT had 70% of total lives updated by the first week of January and 98% of lives by the end of January. And in 2017, MMIT had 65% of total lives updated by the first week of January, 80% of lives by the end of January, and 98% of lives by the end of March.

FDA Approves Second Tissue-Agnostic Drug; Refund Is Available

As the FDA continues to approve drugs targeted toward specific biomarkers, the agency has granted accelerated approval to another tissue-agnostic oncology treatment. While the gene fusion is fairly rare, Loxo Oncology, Inc. and Bayer Corp.'s Vitrakvi (larotrectinib) has shown high overall response rates across multiple solid tumors. Not surprisingly, the medication comes with a high price tag — but also a refund for qualified patients who do not respond within three months of initiating treatment, AIS Health reported.

On Nov. 26, the FDA gave accelerated approval to Vitrakvi for the treatment of adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation; are metastatic or where surgical resection is likely to result in severe morbidity; and have no satisfactory alternative therapies or that have progressed after treatment.

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"It definitely is an exciting development within the oncology treatment arena, but where it's going to fit into treatment" in terms of guidelines and protocols "is yet to be seen," says Beckie Fenrick, Pharm.D., senior partner at RemedyOne.

The drug is available as a capsule, dosed at 100 mg twice daily, as well as a liquid formulation for certain pediatric patients, with dosing 100 mg/m2 twice daily. Bayer set the monthly wholesale acquisition cost for a 30-day supply of 100 mg capsules at $32,800, and the WAC for the liquid formulation at $11,000 monthly.

Multiple programs through TRAK Assist are in place to help people afford the medication:

- TRAK Assist $0 Co-Pay Program will be available for eligible patients with commercial or private insurance.
- VITRAKVI Bridge Program will provide the drug for free to people who have coverage delayed or who have a temporary coverage lapse during the period without coverage.
- TRAK Assist will refer publicly insured patients to third-party assistance programs.
- A patient assistance foundation will help qualified uninsured or underinsured people.

In addition, in a situation where a patient does not have a clinical benefit within 90 days of starting the drug, the cost of up to two months of Vitrakvi will be refunded to each entity that made a payment for the drug — patients, payers and third-party organizations — through the Vitrakvi Commitment Program.

New PBM Models Respond to Pressure, Market Demand

Express Scripts Holding Co. and CVS Health Corp. have in recent months unveiled new programs that appear designed to transition away from the PBM status quo, AIS Health reported.

One factor driving both new programs could be a proposed rule that's still under review by the Office of Management and Budget, which might remove prescription drug rebates' safe-harbor protections from the federal antikickback statute. But one industry expert says it looks less likely that may actually transpire.

"I think it has more to do with the fact, almost regardless of that [potential rule], that rebates going forward potentially are going to be so variable," says David Dross, the leader of Mercer's managed pharmacy practice. He says the PBMs' moves are a response to "marketplace demand" for a different type of pharmacy benefits model.

Express Scripts' new National Preferred Flex Formulary allows it to add to its formulary a newly launched lower-cost alternative to a brand medication — giving members immediate access to that drug — and lets the PBM exclude the innovator brand product from coverage.

Under CVS's new Guaranteed Net Cost model, the company will pass 100% of rebates to plan sponsors and "take accountability for the impact of drug price inflation and shifts in drug mix," the company said in a press release.

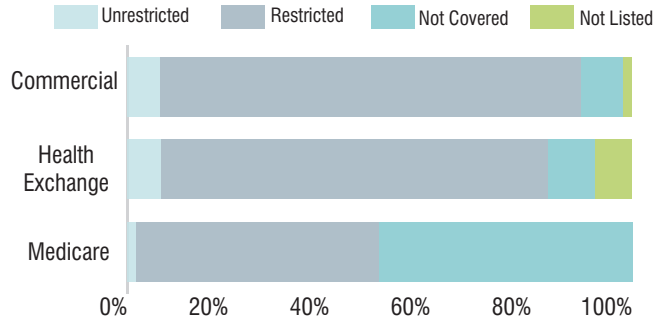
Though the models differ in design and scope, Dross says similar forces are driving them. "I think there's so much buzz in the marketplace around rebates, and what they are or aren't," he says. "People are becoming more conversant about it, so what that does is it sort of shines a light on all of the various entities in the supply chain, including pharma manufacturers."

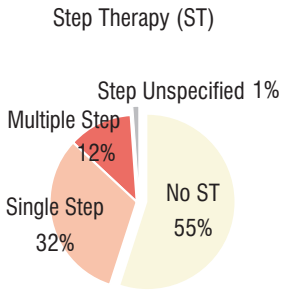
In response to that, manufacturers are experimenting with different approaches to pricing, which move away from the high-list-price, high-rebate paradigm, he explains. "And it kind of puts the pressure on the PBMs to say, 'gee, well, how do we deal with that or address that?'" Dross adds.

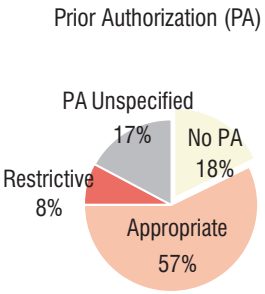
Current Market Access to Hepatitis C Medications

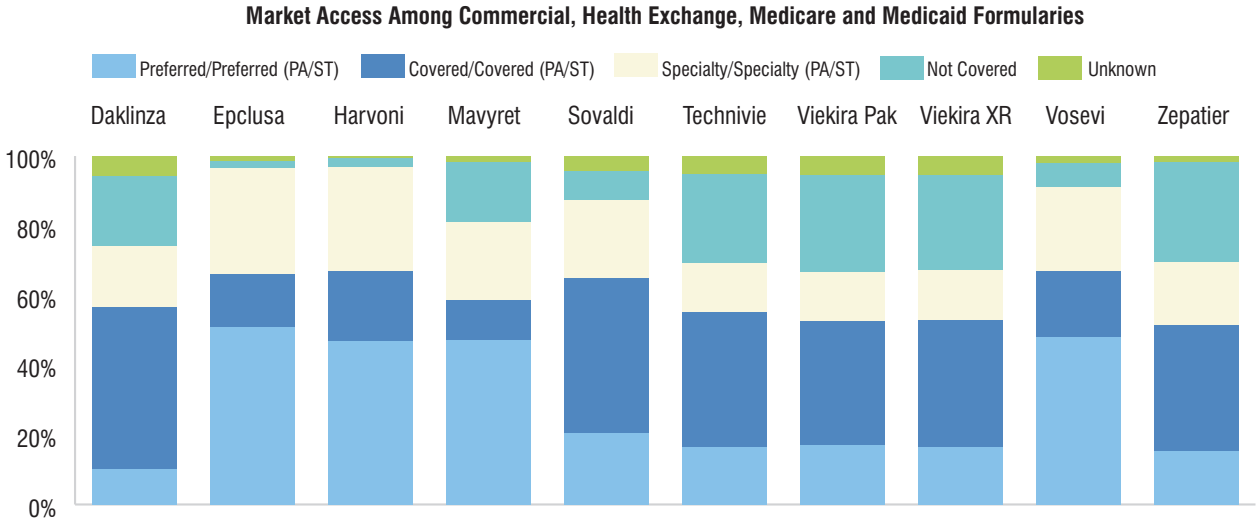
by Jinghong Chen

Hepatitis C medications are covered under the pharmacy benefit with some limitations, most frequently prior authorizations and quantity limits. For all of the drugs on the market, more than half of covered lives are under the preferred tier/preferred with prior authorization or step therapy and covered tier/covered with PA/ST. Payer pharmacy benefit formularies require ST for 45% of the covered lives and PA for 82% of the lives. The graphics below show how hepatitis C medications are covered among commercial health plans, health exchange programs and Medicare and Medicaid programs, and their utilization management restrictions.









NOTE: The number of total covered lives is 302.1 million. The numbers of total covered lives under commercial, health exchange and Medicare formularies are 109.2 million, 10.6 million and 31.9 million, respectively.

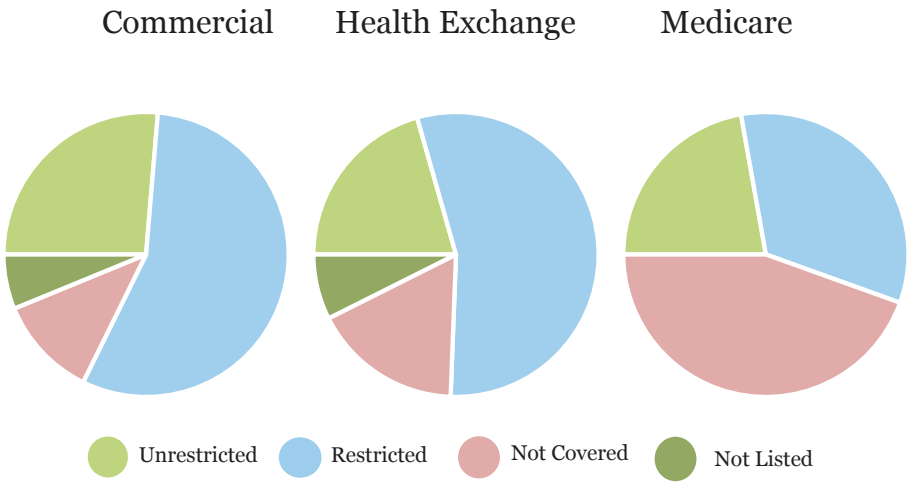
SOURCE: Managed Markets Insight & Technology, LLC database as of December 2018.

Reality Check: **Multiple Sclerosis**

Coverage

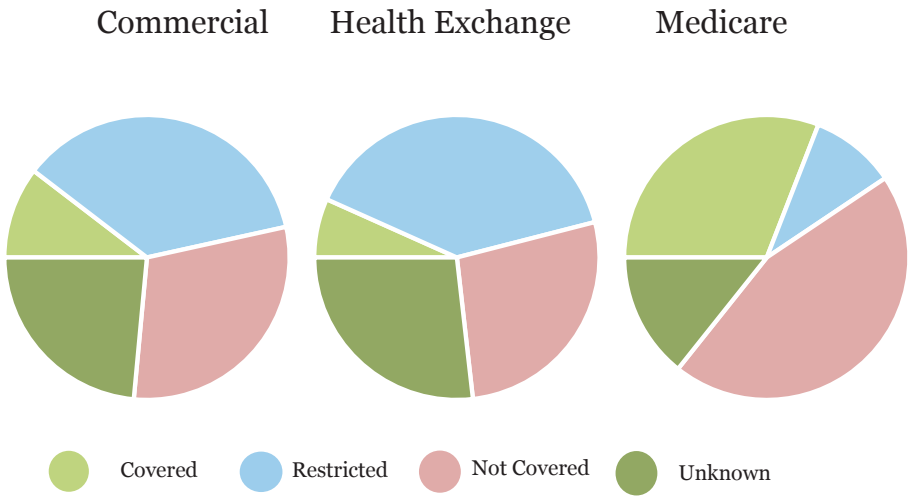
Pharmacy Benefit

More than half of the lives under the pharmacy benefit in commercial and health exchange formularies have utilization management restrictions on multiple sclerosis medications. Across all drugs, almost 45% of beneficiaries under Medicare programs are not covered for at least one of the drugs.



Medical Benefit

Under commercial policies, more than 36% of the lives have utilization management restrictions. Under Medicare policies, about 30% of the lives do not have such restrictions, while 45% of the lives are not covered for at least one of the 14 medications administered under the medical benefit.



Key Players

DATA CURRENT AS OF Q1 2019

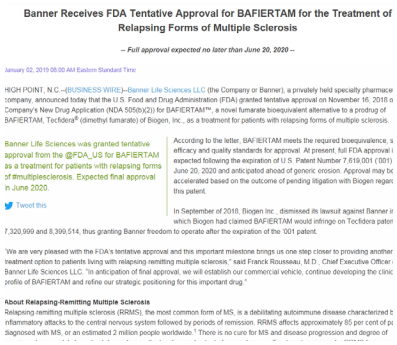
Reality Check: **Multiple Sclerosis**

Trends

FDA Gave Tentative Approval to Bafiertam

In November, the FDA granted tentative approval for Banner Life Sciences LLC's Bafiertam, a fumarate bioequivalent alternative to Biogen, Inc.'s Tecfidera (dimethyl fumarate), for the treatment of patients with relapsing forms of multiple sclerosis.

Via Business Wire



Banner Receives FDA Tentative Approval for BAFIERTAM for the Treatment of Relapsing Forms of Multiple Sclerosis

-- Full approval expected no later than June 20, 2020 --

January 02, 2019 08:00 AM Eastern Standard Time

HIGH POINT, N.C.--(BUSINESS WIRE)--Banner Life Sciences LLC (the Company or Banner), a privately held specialty pharmace company, announced today that the U.S. Food and Drug Administration (FDA) granted tentative approval on November 16, 2018 o Company's New Drug Application (NDA 505(b)(2)) for BAFIERTAM™, a novel fumarate bioequivalent alternative to a prodrug of BAFIERTAM, Tecfidera® (dimethyl fumarate) of Biogen, Inc., as a treatment for patients with relapsing forms of multiple sclerosis.

Banner Life Sciences was granted tentative approval from the @FDA_US for BAFIERTAM as a treatment for patients with relapsing forms of #multiplesclerosis. Expected final approval in June 2020.

Tweet this

According to the letter, BAFIERTAM meets the required bioequivalence, s efficacy and quality standards for approval. At present, full FDA approval i expected following the expiration of U.S. Patent Number 7,619,001 ('001) June 20, 2020 and anticipated ahead of generic erosion. Approval may be accelerated based on the outcome of pending litigation with Biogen regar this patent.

In September of 2010, Biogen Inc., dismissed its lawsuit against Banner i which Biogen had claimed BAFIERTAM would infringe on Tecfidera paten 7,320,999 and 8,399,514, thus granting Banner freedom to operate after the expiration of the '001 patent.

"We are very pleased with the FDA's tentative approval and this important milestone brings us one step closer to providing another treatment option to patients living with relapsing remitting multiple sclerosis," said Franck Rousseau, M.D., Chief Executive Officer Banner Life Sciences LLC. "In anticipation of final approval, we will establish our commercial vehicle, continue developing the clinic profile of BAFIERTAM and refine our strategic positioning for this important drug."

About Relapsing-Remitting Multiple Sclerosis

Relapsing-remitting multiple sclerosis (RRMS), the most common form of MS, is a debilitating autoimmune disease characterized b inflammatory attacks to the central nervous system followed by periods of remission. RRMS affects approximately 85 per cent of pa diagnosed with MS, or an estimated 2 million people worldwide.[1] There is no cure for MS and disease progression and degree of

Biogen to Evaluate Tysabri Extended Dosing

Biogen, Inc. said it started a global Phase 3b clinical trial to evaluate the efficacy and safety of extended interval dosing of Tysabri (natalizumab) every six weeks in patients with relapsing multiple sclerosis. The current approved standard interval dosing regimen is 300 mg every four weeks.

Via Multiple Sclerosis News Today

Biogen Starts Phase 3b Trial to Evaluate Tysabri Extended Interval Dosing in RRMS Patients

JANUARY 7, 2019 BY SANTIAGO GISLER IN NEWS.

Biogen announced the start of a global Phase 3b clinical trial to evaluate the efficacy and

Biogen and Skyhawk Team Up

Biogen, Inc. and Skyhawk Therapeutics, Inc. teamed up to develop new small molecule treatments for neurological diseases, including multiple sclerosis, using Skyhawk's SkySTAR technology platform. Biogen paid $74 million upfront and will have the ability to license products that are the result of the collaboration.

Via pharmaphorum

Pair of deals boosts Biogen's early-stage CNS pipeline

Phil Taylor

January 7, 2019

Biogen has signed a brace of collaborations to expand its central nervous syste (CNS) pipeline, adding new candidates for Alzheimer's, multiple sclerosis and other neurological diseases.

The first of the new deals is a $415 million collaboration with protein degradation specialist C4 Therapeutics, focusing on Alzheimer's, Parkinson's and other neurologic diseases, while Biogen is also paying Skyhawk Therapeutics $74 million upfront to license therapeutic candidates for MS, spinal muscular atrophy (SMA) and other diseases developed using its RNA platform, plus undisclosed milestones.

The two deals continue Biogen's tight focus on neurology – first pursued in 2016 whe it spun off its haemophilia business into Bioverativ (since acquired by Shire) – but contribute to an ongoing effort to reduce the company's reliance on a portfolio of fas maturing MS therapies headed by Tecfidera (dimethyl fumarate) which has started to see sales flatten.

Biogen currently has five potential Alzheimer's treatments and one Parkinson's treatment in development, and analysts have become concerned that its focus on tough-to-treat diseases make its pipeline very high risk despite other projects in stroke, MS, lupus and other diseases.

C4T's platform focuses on the use of small-molecule drugs – called degronimids – tha can target, degrade and clear proteins through the ubiquitin/proteasome pathway.

Reality Check: **Multiple Sclerosis**

Key Findings

More Treatment Approvals

Ocrevus (ocrelizumab), approved by the FDA in 2017, is the fourth infused product approved and the only drug approved to treat progressive forms of multiple sclerosis. It is the only infusible without a black box warning.

Contracting Prevalence

Contracting is prevalent among the interferons, where formulary preference drives choice. The orals are all different molecules. Contracting is expected to occur for these drugs, but not to compete against the other brands. Competitive contracting on all the monoclonal antibodies (MABs), except Tysabri, is also expected.

Coverage Varies

Interferons and Copaxone, as well as its generics, are considered first line in the treatment pathway. There are no true generics for the interferons. But with Copaxone generics, including Glatopa, available, some plans require those to be used. Interferons/Copaxones and orals are generally covered under the pharmacy benefit, although some coverage is seen for interferons under the medical benefit. MABs can be covered under both benefits, while infusible MABs appear most often on the medical benefit policies. All drugs for this indication are considered specialty drugs.

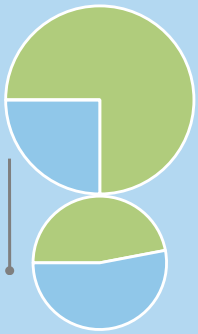
Characteristics

Indications

Multiple Sclerosis

Step-Therapy (ST) Policies

A review of ST policies for payer-controlled formularies:



No ST (75%)

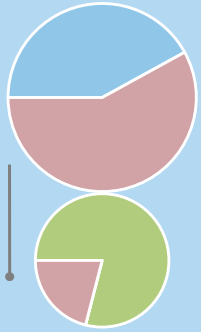
ST (25%)

Single Step (47%)

Multi Step (53%)

Prior-Authorization (PA) Policies

A review of PA policies for payer-controlled formularies:



No PA (42%)

PA (58%)

Appropriate (79%)

Restrictive (21%)

DATA CURRENT AS OF Q1 2019

About AIS Health

The mission of AIS Health — a publishing and information company that has served the health care industry for more than 30 years — is to provide readers with an actionable understanding of the business of health care and pharmaceuticals. AIS Health's in-depth writing covers the companies, people, catalysts and trends that create the richly textured contours of the health care and drug industry.

AIS Health, which maintains journalistic independence from its parent company, MMIT, is committed to integrity in reporting and bringing transparency to health industry data.

Learn more at https://AISHealth.com and https://AISHealthData.com.

About MMIT

MMIT is a product, solutions and advisory company that brings transparency to pharmacy and medical benefit information. MMIT partners with PBMs, payers and pharmaceutical manufacturers from P&T to point of care. We analyze market access trends and market readiness issues, while providing brand and market access solutions to navigate today's rapidly changing healthcare market.

Our team of experts focuses on pharmaceuticals, business drivers, market intelligence and promotional behavior. Our products and services support brands approaching launch, commercialization efforts, pre-P&T market planning, launch strategy and readiness. We partner with hundreds of payers and manufacturers ensuring that our products continually capture and analyze formulary coverage and restriction criteria for more than 98% of all covered lives.

Learn more at https://www.mmitnetwork.com.