AS THE RMS TREATMENT LANDSCAPE CHANGES,

WHAT HAS BEEN YOUR EXPERIENCE WITH THE SAFETY PROFILE OF AUBAGIO?[1]

13 NEW RMS THERAPIES SINCE 2012[2-14]*

Actual size

*As of February 2022.

RMS=relapsing forms of multiple sclerosis.

INDICATION

AUBAGIO® (teriflunomide) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

WARNING: HEPATOTOXICITY AND EMBRYOFETAL TOXICITY

- **Clinically significant and potentially life-threatening liver injury, including acute liver failure requiring transplant, has been reported in patients treated with AUBAGIO in the postmarketing setting. Concomitant use of AUBAGIO with other hepatotoxic drugs may increase the risk of severe liver injury.**
- **Obtain transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy. Monitor ALT levels at least monthly for 6 months after starting AUBAGIO. If drug-induced liver injury is suspected, discontinue AUBAGIO and start an accelerated elimination procedure with cholestyramine or activated charcoal. AUBAGIO is contraindicated in patients with severe hepatic impairment. Patients with pre-existing liver disease may be at increased risk of developing elevated serum transaminases when taking AUBAGIO.**
- **AUBAGIO is contraindicated for use in pregnant women and in women of reproductive potential who are not using effective contraception because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals at plasma teriflunomide exposure lower than that in humans. Exclude pregnancy before the start of treatment with AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure after AUBAGIO treatment. Stop AUBAGIO and use an accelerated drug elimination procedure if the patient becomes pregnant.**

Please see additional Important Safety Information throughout and accompanying **Full Prescribing Information**, including **boxed WARNING**.

Once-daily AUBAGIO® (teriflunomide) 14 mg tablets

AUBAGIO is available in 14 mg and 7 mg tablets.

SAFETY PROFILE ESTABLISHED OVER 4 CLINICAL TRIALS[1,15,16]

AUBAGIO® (teriflunomide) was studied in 3 Phase III clinical trials and 1 Phase II clinical trial[1]

4 clinical trials[1]

2047 patients studied[1]

>3044 patient-years of AUBAGIO exposure[1,15]

Incidences of and discontinuation rates due to most common AEs[1,15,16]

AEs occurring in ≥10% of patients and ≥2% in comparison to placebo

	AUBAGIO 14 mg (N=1002)		AUBAGIO 7 mg (N=1045)		Placebo (N=997)	
Adverse events	Incidence[1]	Discontinuation[15,16]	Incidence[1]	Discontinuation[15,16]	Incidence[1]	Discontinuation[15,16]
Headache, %	16	0	18	0	15	0.3
ALT increase, %*	15	2.6	13	3.3	9	2.3
Diarrhea, %	14	0.4	13	0.5	8	0.1
Alopecia, %†	13	1.3	10	0.2	5	0.1
Nausea, %	11	0.3	8	<0.1	7	0

- Diarrhea and nausea associated with AUBAGIO 14 mg were generally mild to moderate in severity[16]
- Most cases of hair thinning/loss were mild to moderate, had a median time to onset of 99 days, and improved without corrective therapy while patients remained on study treatment[16]

Serious adverse events

- Serious adverse events occurred in 13%, 12%, and 12% of patients in the AUBAGIO 14 mg, AUBAGIO 7 mg, and placebo groups, respectively[15‡]
  - Serious adverse events reported in AUBAGIO clinical trials included hepatotoxicity, infections, peripheral neuropathy, and blood pressure effects[1]
  - Cases of bone marrow effects, hypersensitivity, skin reactions including a fatal case of toxic epidermal necrolysis, respiratory effects, drug-induced liver injury, and a fatal case of drug reaction with eosinophilia and systemic symptoms have been reported in patients taking AUBAGIO in the postmarketing setting[1]
  - Medications like AUBAGIO may cause patients to be more susceptible to infections, including opportunistic infections[1]
- Four cardiovascular deaths, including 3 sudden deaths and 1 myocardial infarction in a patient with a history of hyperlipidemia and hypertension, were reported among approximately 2600 patients exposed to AUBAGIO in the premarketing database[1]
  - A relationship between AUBAGIO and cardiovascular death has not been established

*Patients were to be withdrawn from study treatment and an accelerated elimination procedure performed when ALT >3 times the upper limit of normal (ULN) was repeated within 48 hours, per protocol.[1]

†The term alopecia is used to describe any type of hair loss. Most cases of alopecia were reported as hair thinning, decreased hair density, or hair loss.[16]

‡Serious AEs were determined by the physician to be medically important, require or prolong a hospitalization, or be life-threatening.[16]

AE=adverse event; ALT=alanine aminotransferase.

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SAFETY DATA REINFORCED OVER 17 YEARS, INCLUDING 9 YEARS POSTMARKETING[1,16-23]

Consistent safety data from 4 clinical trials[1,15,16]

Phase II (~12 years of extension data)	TEMSO (~8 years of extension data)	TOPIC (~5 years of extension data)	TOWER (~6 years of extension data)
Most common AEs were nasopharyngitis, hypoesthesia, fatigue, muscular weakness, and upper respiratory tract infection[16] • Serious AEs*: 48.1% of AUBAGIO® (teriflunomide) 7 mg and 40.9% of AUBAGIO 14 mg patients	**AEs occurred in ~93% of patients; overall discontinuation rates due to AEs were 12.6%[16,17]** • Serious AEs were 25% across treatment groups	**AEs occurred in 79% of patients over the extension period[18]** • Overall, 13.5% of patients experienced serious AEs and 5.9% discontinued treatment due to AEs	**AEs occurred in ~79% of patients and overall discontinuation rates due to AEs were <8%[19]** • Serious AEs: <11% of patients across treatment groups • Most common AEs: nasopharyngitis (14%), headache (9%), diarrhea (9%), hair thinning (8%), and back pain (7%)

*Serious AEs were determined by the physician to be medically important, require or prolong a hospitalization, or be life threatening.[16]

>90K

Over 90,000 patients have been prescribed AUBAGIO since its US approval. What has your experience been with the well-established safety profile of AUBAGIO?[1,16]

Looking for tools that can help your patients understand common side effects? Click here to access our video library.

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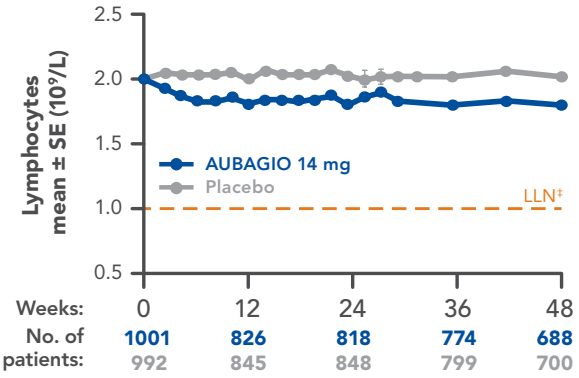
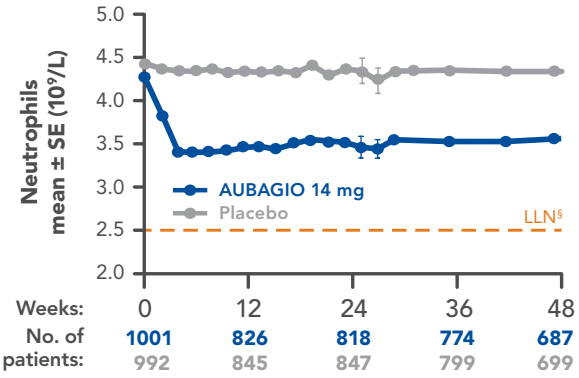
WHITE BLOOD CELL COUNTS REMAINED WITHIN NORMAL RANGE ON AUBAGIO[15]

Mean lymphocyte and neutrophil counts remained within normal ranges in the pooled core clinical trials for AUBAGIO® (teriflunomide)[15]*

Mean lymphocyte counts[16†]



Mean neutrophil counts[16†]



- The mean decrease in lymphocyte and neutrophil cell counts was approximately 15%[1]
- AUBAGIO 7 mg also demonstrated similar effects on lymphocyte and neutrophil counts[16]

There was no increase in serious infections with AUBAGIO[1]

- No overall increase in serious infections with AUBAGIO versus placebo was observed in clinical trials[1]
  - Medications such as AUBAGIO may cause patients to be more susceptible to infections
- One fatal case of *Klebsiella* pneumonia sepsis occurred in a patient taking AUBAGIO 14 mg for 1.7 years[1]
- In clinical trials for AUBAGIO, cytomegalovirus hepatitis reactivation and cases of tuberculosis have been observed[1]
- A mean decrease in white blood cell count of approximately 15% (mainly neutrophils and lymphocytes) and in platelet count of approximately 10% was observed in clinical trials[1]
- AUBAGIO has no PML in its Prescribing Information[1]
- AUBAGIO has a warning and precaution for live vaccines: no clinical data are available on the efficacy and safety of live vaccinations in patients taking AUBAGIO. Vaccination with live vaccines is not recommended. The long half-life of AUBAGIO should be considered when contemplating administration of a live vaccine after stopping AUBAGIO[1]
  - There is no data on inactivated vaccines included in the Prescribing Information for AUBAGIO

*Data were pooled from 4 randomized, placebo-controlled trials (the Phase II proof-of-concept, TEMSO, TOWER, and TOPIC).[15,16]
†For Weeks 26 and 28, only data from Phase II study were available.[16]
‡Normal range for general population: 1.0–4.0 x 10^9/L.[16]
§Normal range for general population: 2.5–7.5 x 10^9/L.[16]
PML=progressive multifocal leukoencephalopathy.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS

- **Bone Marrow Effects/Immunosuppression Potential/Infections:** Decreases in white blood cell counts, mainly of neutrophils and lymphocytes, and platelets have been reported with AUBAGIO. Thrombocytopenia, including rare cases with platelet counts less than 50,000/mm^3, has been reported in the postmarketing setting.

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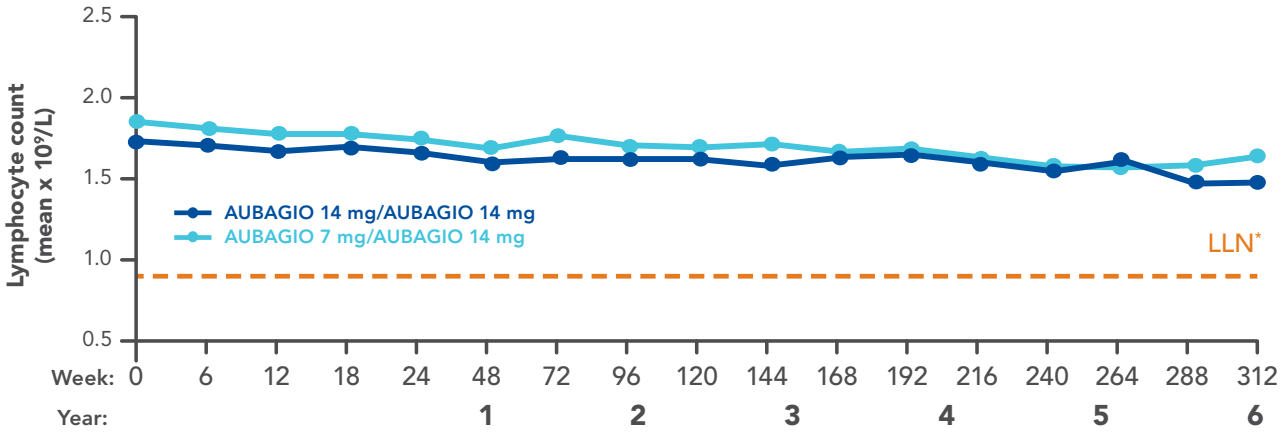
LYMPHOCYTE COUNTS REMAINED STABLE OVER TIME[16]

Mean lymphocyte counts with AUBAGIO® (teriflunomide) remained stable and within normal range for up to 6 years in the TEMSO extension trial[16]

Mean lymphocyte counts over time[16]



Additional extension trial results for AUBAGIO 14 mg and 7 mg

- **TOPIC extension trial:** Mean lymphocyte count remained ~1.5x10⁹/L for the 132 weeks studied (LLN=1.0x10⁹/L)[18]
- **TOWER extension trial:** Mean white blood cell count remained ~6x10⁹/L for the 72 weeks studied (LLN=3.8x10⁹/L)[16]

*Normal range for general population: 1.0–4.0 × 10⁹/L.[16]
DMT=disease-modifying therapy; LLN=lower limit of normal.

When selecting your RMS patient's next DMT, consider your experience with the lymphocyte levels of patients on AUBAGIO.

IMPORTANT SAFETY INFORMATION (continued)
WARNINGS AND PRECAUTIONS (continued)

- **Bone Marrow Effects/Immunosuppression Potential/Infections:**
  Obtain a complete blood cell count within 6 months before starting treatment, with further monitoring based on signs and symptoms of bone marrow suppression. AUBAGIO is not recommended for patients with severe immunodeficiency, bone marrow disease, or severe uncontrolled infections. Tuberculosis (TB) has been observed in clinical studies of AUBAGIO. Before starting treatment, screen patients for latent TB infection with a tuberculin test. Treatment in patients with acute or chronic infections should not be started until the infection(s) is resolved. Administration of live vaccines is not recommended. The risk of malignancy, particularly lymphoproliferative disorders, or infection may be increased with the use of some medications with immunosuppressive potential, including teriflunomide.

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INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

AUBAGIO® (teriflunomide) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

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- **Obtain transaminase and bilirubin levels within 6 months before initiation of AUBAGIO therapy. Monitor ALT levels at least monthly for 6 months after starting AUBAGIO. If drug-induced liver injury is suspected, discontinue AUBAGIO and start an accelerated elimination procedure with cholestyramine or activated charcoal. AUBAGIO is contraindicated in patients with severe hepatic impairment. Patients with pre-existing liver disease may be at increased risk of developing elevated serum transaminases when taking AUBAGIO.**
- **AUBAGIO is contraindicated for use in pregnant women and in women of reproductive potential who are not using effective contraception because of the potential for fetal harm. Teratogenicity and embryolethality occurred in animals at plasma teriflunomide exposure lower than that in humans. Exclude pregnancy before the start of treatment with AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure after AUBAGIO treatment. Stop AUBAGIO and use an accelerated drug elimination procedure if the patient becomes pregnant.**

CONTRAINDICATIONS

- Patients with severe hepatic impairment.
- Pregnant women and females of reproductive potential not using effective contraception.
- Patients with a history of hypersensitivity reaction to teriflunomide, leflunomide, or to any of the inactive ingredients in AUBAGIO.
- Co-administration with leflunomide.

WARNINGS AND PRECAUTIONS

- **Hepatotoxicity:** Clinically significant liver injury, which could be life-threatening, can occur at any time during treatment with AUBAGIO. Patients with pre-existing acute or chronic liver disease, or those with serum ALT >2 times the upper limit of normal (ULN) before initiating treatment, should not normally be treated with AUBAGIO. In clinical trials, if ALT elevation was >3 times the ULN on 2 consecutive tests, patients discontinued AUBAGIO and underwent accelerated elimination. Consider additional monitoring if co-administering AUBAGIO with other potentially hepatotoxic drugs; monitor patients who develop symptoms suggestive of hepatic dysfunction (eg, unexplained nausea, vomiting, abdominal pain, fatigue, anorexia, or jaundice and/or dark urine).
- **Embryofetal Toxicity:** AUBAGIO may cause fetal harm when administered in pregnant women. Teratogenicity and embryofetal lethality occurred in animal reproduction studies in multiple animal species at plasma teriflunomide exposures similar to or lower than that in humans at the maximum human recommended dose of 14 mg/day. AUBAGIO is contraindicated for use in pregnant women and females of reproductive potential not using effective contraception.

  Exclude pregnancy before starting AUBAGIO in females of reproductive potential. Advise females of reproductive potential to use effective contraception during AUBAGIO treatment and during an accelerated drug elimination procedure (AEP) after AUBAGIO treatment. If a woman becomes pregnant while taking AUBAGIO, stop treatment, apprise patient of the potential risk to a fetus, and perform an AEP to achieve an AUBAGIO plasma concentration of <0.02 mg/L. Upon discontinuing AUBAGIO, it is recommended all females of reproductive potential undergo an AEP.

  Women receiving AUBAGIO who wish to become pregnant must discontinue AUBAGIO and undergo an AEP, until plasma concentrations of AUBAGIO are <0.02 mg/L. Men wishing to father a child should also stop AUBAGIO and either undergo an AEP or wait until plasma concentration of AUBAGIO is <0.02 mg/L.

  Women who become pregnant while taking AUBAGIO may enroll in the AUBAGIO pregnancy registry by calling 1-800-745-4447, option 2.

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IMPORTANT SAFETY INFORMATION (continued)

WARNINGS AND PRECAUTIONS (continued)

- **Procedure for Accelerated Elimination of Teriflunomide:** Teriflunomide is eliminated slowly from the plasma—it takes an average of 8 months, or up to 2 years, to reach plasma concentrations <0.02 mcg/mL. Elimination may be accelerated by administration of cholestyramine or activated charcoal, but this may cause disease activity to return in patients who were responding to AUBAGIO.
- **Bone Marrow Effects/Immunosuppression Potential/Infections:** Decreases in white blood cell counts, mainly of neutrophils and lymphocytes, and platelets have been reported with AUBAGIO. Thrombocytopenia, including rare cases with platelet counts less than 50,000/mm^3, has been reported in the postmarketing setting. Obtain a complete blood cell count within 6 months before starting treatment, with further monitoring based on signs and symptoms of bone marrow suppression. AUBAGIO is not recommended for patients with severe immunodeficiency, bone marrow disease, or severe uncontrolled infections. Tuberculosis (TB) has been observed in clinical studies of AUBAGIO. Before starting treatment, screen patients for latent TB infection with a tuberculin test. Treatment in patients with acute or chronic infections should not be started until the infection(s) is resolved. Administration of live vaccines is not recommended. The risk of malignancy, particularly lymphoproliferative disorders, or infection may be increased with the use of some medications with immunosuppressive potential, including teriflunomide.
- **Hypersensitivity Reactions:** AUBAGIO can cause anaphylaxis and severe allergic reactions. Signs and symptoms have included dyspnea, urticaria, and angioedema including lips, eyes, throat, and tongue. Inform patients of the signs and symptoms of anaphylaxis and angioedema.
- **Serious Skin Reactions:** Cases of serious skin reactions, sometimes fatal, including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported with AUBAGIO. Fatal outcomes were reported in one case of TEN and one case of DRESS. Inform patients of the signs and symptoms of a serious skin reaction and instruct them to discontinue AUBAGIO and seek immediate medical care. Unless the reaction is clearly not drug-related, discontinue AUBAGIO and begin accelerated elimination immediately. In such cases, patients should not be re-exposed to teriflunomide.
- **Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS):** DRESS, also known as multiorgan hypersensitivity, has occurred with AUBAGIO. One fatal case of DRESS that occurred within 34 days of initiation of AUBAGIO treatment has been reported in the postmarketing setting. DRESS typically, although not exclusively, presents with fever, rash, lymphadenopathy and/or facial swelling, in association with other organ system involvement, such as hepatitis, nephritis, hematologic abnormalities, myocarditis, or myositis, sometimes resembling an acute viral infection. Eosinophilia is often present. This disorder is variable in its expression, and other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity (eg, fever, lymphadenopathy) may be present even though rash is not evident. If such signs or symptoms are present, the patient should be evaluated immediately.

  Discontinue AUBAGIO, unless an alternative etiology for the signs or symptoms is established, and begin an accelerated elimination procedure immediately. In such cases, patients should not be re-exposed to teriflunomide.
- **Peripheral Neuropathy:** Peripheral neuropathy, including polyneuropathy and mononeuropathy, has been reported with AUBAGIO. Age >60 years, concomitant neurotoxic medications, and diabetes may increase the risk. If peripheral neuropathy is suspected, consider discontinuing treatment and performing accelerated elimination.
- **Increased Blood Pressure:** Blood pressure increases and hypertension have occurred with AUBAGIO. Measure blood pressure at treatment initiation and manage any elevations during treatment.
- **Respiratory Effects:** Interstitial lung disease (ILD), including acute interstitial pneumonitis, has been reported with AUBAGIO. ILD may be fatal and may occur acutely at any time during therapy with a variable clinical presentation. If discontinuation of the drug is necessary, consider initiation of an accelerated elimination procedure.
- **Pancreatitis in Pediatric Patients:** AUBAGIO is not approved for use in pediatric patients. In a pediatric clinical trial, cases of pancreatitis were observed in patients receiving AUBAGIO. If pancreatitis is suspected, discontinue teriflunomide and start an accelerated elimination procedure.

Adverse Reactions: The most frequent adverse reactions (≥10% and ≥2% greater than placebo) with AUBAGIO 7 mg and 14 mg and placebo, respectively, were headache (18% and 16% vs 15%), ALT increased (13% and 15% vs 9%), diarrhea (13% and 14% vs 8%), alopecia (10% and 13% vs 5%), and nausea (8% and 11% vs 7%).

Drug Interactions: Monitor patients when teriflunomide is coadministered with warfarin, or with drugs metabolized by CYP1A2, CYP2C8, substrates of OAT3 transporters, substrates of BCRP, or OATP1B1/1B3 transporters.

Use in Specific Populations: Women should not breastfeed during treatment with AUBAGIO.

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One pill, once a day[1]

Actual size

IN AN EVER-CHANGING LANDSCAPE OF RMS TREATMENTS, CONSIDER THE SAFETY PROFILE OF AUBAGIO

17+ years

of combined clinical trial and real-world experience[1,16-23]

>90,000 patients were prescribed AUBAGIO® (teriflunomide) since US approval[16]

White blood cell counts remained in the normal range[16]*

*Normal lymphocyte count range for general population: 1.0–4.0 × 10^9/L. Normal neutrophil count range for general population: 2.5–7.5 × 10^9/L.[16]

WHEN CHOOSING AN RMS TREATMENT, THINK ABOUT YOUR EXPERIENCE WITH THE SAFETY PROFILE OF AUBAGIO.[1]

Download this form to get started with AUBAGIO

BOXED WARNING: HEPATOTOXICITY AND EMBRYOFETAL TOXICITY

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Please see additional Important Safety Information on the previous pages and accompanying **Full Prescribing Information**, including **boxed WARNING.**

References: 1. AUBAGIO (teriflunomide) [package insert]. Cambridge, MA: Genzyme Corporation. **2.** Tecfidera (dimethyl fumarate) [package insert]. Cambridge, MA: Biogen Idec Inc.; January 2021. **3.** Copaxone (glatiramer acetate injection) [package insert]. North Wales, PA: TEVA Pharmaceuticals USA, Inc.; July 2020. **4.** Plegridy (peginterferon beta-1a) [package insert]. Cambridge, MA: Biogen Inc.; January 2021. **5.** LEMTRADA (alemtuzumab) [package insert]. Cambridge, MA: Genzyme Corporation. **6.** Glatopa (glatiramer acetate injection) [package insert]. Princeton, NJ: Sandoz Inc.; July 2020. **7.** Ocrevus (ocrelizumab) [package insert]. South San Francisco, CA: Genentech, Inc.; March 2021. **8.** Mavenclad (cladribine) [package insert]. Rockland, MA: EMD Serono, Inc.; April 2019. **9.** Mayzent (siponimod) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; July 2020. **10.** Zeposia (ozanimod) [package insert]. Summit, NJ: Bristol Myers Squibb; March 2020. **11.** Bafiertam (monomethyl fumarate) [package insert]. High Point, NC: Banner Life Sciences LLC; April 2020. **12.** Kesimpta (ofatumumab) [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corp; August 2020. **13.** Vumerity (diroximel fumarate) [package insert]. Cambridge, MA: Biogen Idec Inc.; August 2020. **14**. Ponvory (ponesimod) [package insert]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2021. **15.** Comi G, Freedman MS, Kappos L, et al. Pooled safety and tolerability data from four placebo-controlled teriflunomide studies and extensions. *Mult Scler Relat Disord.* 2016;5:97-104. **16.** Data on file, Sanofi. **17.** O'Connor P, Comi G, Freedman MS, et al; for the Teriflunomide Multiple Sclerosis Oral (TEMSO) Trial Group and the MRI-AC in Houston, Texas. Long-term safety and efficacy of teriflunomide: nine-year follow-up of the randomized TEMSO study. *Neurology.* 2016;86(10):920-930. **18**. Miller AE, Vermersch P, Kappos L, et al; on behalf of the TOPIC study group. Long-term outcomes with teriflunomide in patients with clinically isolated syndrome: results of the TOPIC extension study. *Mult Scler Relat Disord.* 2019;33:131-138. **19.** Miller AE, Olsson TP, Wolinsky JS, et al; on behalf of the TOWER investigators. Long-term safety and efficacy of teriflunomide in patients with relapsing multiple sclerosis: results from the TOWER extension study. *Mult Scler Relat Disord.* 2020;46:102438. https://doi.org/10.1016/j.msard.2020.102438. **20.** O'Connor P, Wolinsky JS, Confavreux C, et al; for the TEMSO Trial Group. Randomized trial of oral teriflunomide for relapsing multiple sclerosis. *N Engl J Med.* 2011;365(14):1293-1303. **21.** O'Connor PW, Li D, Freedman MS, et al; on behalf of the Teriflunomide Multiple Sclerosis Trial Group University of British Columbia MS/MRI Research Group. A phase II study of the safety and efficacy of teriflunomide in multiple sclerosis with relapses. *Neurology.* 2006;66(6):894-900. **22.** Confavreux C, O'Connor P, Comi G, et al; for the TOWER Trial Group. Oral teriflunomide for patients with relapsing multiple sclerosis (TOWER): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol.* 2014;13(3):247-256. **23.** Miller AE, Wolinsky JS, Kappos L, et al; for the TOPIC Study Group. Oral teriflunomide for patients with a first clinical episode suggestive of multiple sclerosis (TOPIC): a randomised, double-blind, placebo-controlled, phase 3 trial. *Lancet Neurol.* 2014;13(10):977-986.

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Vermont Prescribers may click here for Average Wholesale Price Disclosure.

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