Gilenya (fingolimod)
Effective 04/17/19

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☒ Prior Authorization ☒ Quantity Limit ☐ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview
Gilenya is a sphingosine 1-phosphate receptor modulator 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 patients 10 years of age and older.

Coverage Guidelines
Approval may be granted when the following criteria are met:

- The member has a diagnosis of a relapsing form of MS **AND**
- Patient is a new AllWays Health Partners member and has already been started and stabilized on fingolimod for an approved indication
  OR
- The member has a diagnosis of a relapsing form of MS **AND**
- The prescribing physician is a neurologist or MS specialist

Continuation of Therapy
Reauthorization requires physician documentation of improvement of overall disease activity, including a reduction in clinical exacerbations and/or prevention of worsening of physical disability.

Limitations
1. Approvals will be granted for 12 months
2. The following quantity limits apply:
   a. A quantity limit of 30 capsules per 30 days
3. Fingolimod is contraindicated in the following scenarios:
   a. Recent (within the last 6 months) occurrence of: MI, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure

b. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
c. Baseline QTc interval ≥500 ms
d. Treatment with Class Ia or Class III anti-arrhythmic drugs

Appendix

Recommended Dosing: Relapsing forms of multiple sclerosis:

Adult Dose	Pediatric Dose
Treatment of patients with relapsing forms of MS to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability: **One capsule (0.5 mg) orally once daily.**	Safety and efficacy have not been established.

First Dose Monitoring:

- Observe all patients for signs and symptoms of bradycardia for at least 6 hours after 1st dose with hourly pulse and blood pressure measurement. Obtain ECG prior to dosing and at the end of the observation period.
- Patients who have a heart rate 6-hours post-dose of <45 bpm, the heart rate 6 hours post-dose is at the lowest value post-dose (i.e., suggesting the max pharmacodynamic effect on the heart may nto have occurred), and whose ECG 6 hours post-dose shows new onset 2nd-degree or higher AV block should be monitored until resolution of the finding. Patients at lowest post-dose heart rate at the end of the observation period should be monitored until heart rate increases.
- In patients experiencing symptomatic bradycardia, begin continuous ECG monitoring until the symptoms have resolved; if pharmacological intervention is required to treat bradycardia, continuous ECG monitoring should continue overnight in a medical facility, and 1st-dose monitoring procedures should be repeated for the 2nd dose.
- Patients with some preexisting conditions (e.g., ischemic heart disease, history of myocardial infarction, CHF, history of cardiac arrest, cerebrovascular disease, uncontrolled hypertension, history of symptomatic bradycardia, history of recurrent syncope, severe untreated sleep apnea, AV block, sinoatrial heart block) may poorly tolerate the fingolimod-induced bradycardia or experience serious rhythm disturbances after the first dose. Prior to treatment, these patients should have a cardiac evaluation, and, if treated with fingolimod, should be monitored overnight with continuous ECG in a medical facility after the first dose.
- Patients with prolonged QTc interval at baseline or during the observation period or taking drugs with known risk of torsades de pointes should be observed overnight with continuous ECG monitoring.

Re-initiation of Therapy Following Discontinuation:

- If therapy is discontinued for more than 14 days, after the first month of treatment, reintroduction of fingolimod may result in recurrence of the effects on heart rate and AV conduction. First dose monitoring for the initial retreatment dose should apply.
- Within the first 2 weeks of therapy, first dose monitoring is recommended for interruptions of one day or more.
- During weeks 3 or 4, first dose monitoring is recommended for interruptions of more than 7 days.

References

1. Gilenya® [package insert]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2019 Jan.

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3. Doggrell SA. Oral fingolimod for relapsing-remitting multiple sclerosis. Expert Opin Pharmacother. 2010;11(10):1777-81.
4. National Institute for Clinical Excellence (NICE). Multiple sclerosis: national clinical guideline for diagnosis and management in primary and secondary care. 2003. Available from: http://www.nice.org.uk/nicemedia/live/10930/46699/46699.pdf.
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8. Gilenya® [Risk Evaluation and Mitigation Strategy]. East Hanover (NJ): Novartis Pharmaceuticals Corporation; 2010 Sept.
9. Goodin DS, Frohman EM, Garmany GP, et al. Disease modifying therapies in multiple sclerosis: Subcommittee of the American Academy of Neurology and the Multiple Sclerosis Council for Clinical Practice Guidelines. Neurology. 2002;58(2):169-78.
10. Goodin DS, Frohman EM, Hurwitz B, O'Connor PW, Oger JJ, Reder AT, et al. Neutralizing antibodies to interferon beta: Assessment of their clinical and radiographic impact: An evidence report: Report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology. 2007;68(13):977-84.
11. Gever J. FDA puts new limits on oral MS drug. MedPage Today. 2012 May 14. Available at: http://www.medpagetoday.com/Neurology/MultipleSclerosis/32675?utm_source=breaking-news&utm_medium=email&utm_campaign=breaking-news
12. Oh J, O'Connor PW. Safety, tolerability and efficacy of oral therapies for relapsing-remitting multiple sclerosis. CNS Drugs. 2013;27:591-609.
13. Calabresi PA, Radue EW, Goodin D, Jeffery D, Rammohan KW, Reder AT, et al. Safety and efficacy of fingolimod in patients with relapsing-remitting multiple sclerosis (FREEDOMS II): a double-blind, randomized, placebo-controlled, phase 3 trial. Lancet Neurology. 204;13(6):545-56.

Review History

04/25/11 – Reviewed
06/06/11 – Effective
04/23/12 – Reviewed
04/22/13 – Reviewed
11/04/13 – Updated (removed injectable requiremen; 09/23/13 P&T Meeting)
04/28/14 – Reviewed
04/27/15 – Reviewed
04/25/16 – Reviewed
04/24/16 – Reviewed
04/17/19 – Reviewed in P&T Meeting

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