

Multiple Sclerosis Agents Step Therapy with Quantity Limit Program Summary

This program is implemented on FlexRx Closed, FlexRx Open, FocusRx, GenRx Closed, GenRx Open, Health Insurance Marketplace, and KeyRx formularies.

This is a FlexRx Standard and GenRx Standard program.

The BCBS MN Step Therapy Supplement also applies to this program for all Commercial/HIM lines of business.

POLICY REVIEW CYCLE

Effective Date 06-01-2024

Date of Origin

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Aubagio® (teriflunomide)*	Treatment of patients with relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	*generic equivalent available	1
Tablet			
Avonex® (interferon β- 1a)	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		2
Injection for intramuscular use			
Bafiertam® (monomethyl fumarate)	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		3
Delayed- release capsule			
Betaseron® (interferon β- 1b)	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		4
Injection for subcutaneous use			
Copaxone® (glatiramer acetate)*	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	*generic equivalent available	5

Agent(s)	FDA Indication(s)	Notes	Ref#
Injection for subcutaneous use			
Extavia®	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active		6
(interferon β- 1b)	secondary progressive disease, in adults		
Injection for subcutaneous use			
Gilenya®	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active	*generic equivalent available	7
(fingolimod)*	secondary progressive disease, in patients 10 years of age and older		
Capsule			
Glatopa®	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active		8
(glatiramer acetate)	secondary progressive disease, in adults		
Injection for subcutaneous use			
Kesimpta®	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active		9
(ofatumumab)	secondary progressive disease, in adults		
Injection for subcutaneous use			
Mavenclad®	Treatment of relapsing forms of multiple sclerosis (MS), to include		10
(cladribine)	relapsing-remitting disease and active secondary progressive disease in adults		
Tablet	Because of its safety profile, use of Mavenclad is generally recommended for patients who have had an inadequate response to, or are unable to tolerate, an alternative drug indicated for the treatment of MS		
	Limitation of Use: Mavenclad is not recommended for use in patients with clinically isolated syndrome (CIS) because of its safety profile		
Mayzent®	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active		11
(siponimod)	secondary progressive disease, in adults		
Tablet			
Plegridy®	Treatment of relapsing forms of multiple sclerosis (MS), to include		12
(peginterferon β-1a)	clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		
Injection for subcutaneous			

Agent(s)	FDA Indication(s)	Notes	Ref#
use or intramuscular use			
Ponvory® (ponesimod)	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		27
Tablet			
Rebif® (interferon β-1b) Injection for	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		13
subcutaneous use			
Tascenso® (fingolimod) Oral	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		29
disintegrating tablet			
Tecfidera® (dimethyl fumarate)* Capsule	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults	*generic equivalent available	14
Vumerity®	Treatment of relapsing forms of multiple sclerosis (MS), to include		15
(diroximel fumarate)	clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults		
Delayed- release capsule			

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Multiple sclerosis (MS) is a disorder of the central nervous system (CNS) characterized by demyelization, inflammation, and degenerative changes. Most people with MS experience relapses and remissions of neurological symptoms, particularly early in the disease, and clinical events are usually associated with areas of CNS inflammation. Gradual worsening or progression, with or without subsequent acute attacks of inflammation or radiological activity, may take place early, but usually becomes more prominent over time. While traditionally viewed as a disease solely of CNS white matter, more advanced imaging techniques have demonstrated significant early and ongoing CNS gray matter damage as well.(16) Those diagnosed with MS may have many fluctuating and disabling symptoms (including, but not limited to, fatigue, pain, bladder and bowel issues, sexual dysfunction, movement and coordination problems, visual disturbances, and cognition
and emotional changes.(30) There are currently four major types of MS: clinically

		ing-remitting MS (RRMS), primary progressive MS	
Relapsing remitting multiple sclerosis (RRMS)	(PPMS), and secondary progressive MS (SPMS).(23) RRMS is characterized by clearly defined attacks (relapses) of new or increasing neurologic symptoms. These relapses are followed by periods of partial or complete recovery. There is no or minimal disease progression during the periods between disease relapses, though individual relapses may result in severe residual disability. The course of MS varies, however, about 85-90% of individuals with MS demonstrate a relapsing pattern at onset, which transitions over time in the majority of untreated patients to a pattern of progressive worsening with few or no relapses or MRI activity.(23)		
Secondary progressive multiple sclerosis (SPMS)	deterioration in function, unrelat	time the disease enters a stage of steady ted to acute attacks. Most people with RRMS will re is no progressive worsening of symptoms over time sion.(23)	
2017 McDonald Criteria for the diagnosis of Multiple Sclerosis:	evidence have evolved over time	clerosis combining clinical, imaging, and laboratory e. The increasing incorporation of paraclinical , to supplement clinical findings has allowed earlier, ic diagnosis.(21,22)	
	The diagnosis of MS requires elimof dissemination of lesions in the	mination of more likely diagnoses and demonstration e CNS in space and time.(21)	
	Misdiagnosis of multiple sclerosis remains an issue in clinical practice, and several factors that potentially increase this risk have been identified. Multiple sclerosis has heterogeneous clinical and imaging manifestations, which differ between patients over time. There is no single pathognomonic clinical feature or diagnostic test; diagnosis of multiple sclerosis relies on the integration of clinical, imaging, and laboratory findings. MRI abnormalities associated with other diseases and non-specific MRI findings, which are common in the general population, can be mistaken for multiple sclerosis. The increasingly strong focus on timely diagnosis to alleviate uncertainty for patients and allow initiation of disease-modifying therapies might also increase the risk of misdiagnosis.(21)		
	With increasing availability and use of MRI, incidental T2 hyperintensities on brain imaging are common, the subset of individuals with MRI findings that are strongly suggestive of multiple sclerosis lesions but with no neurological manifestations or other clear-cut explanation are said to have radiologically isolated syndrome. There is no consensus on whether patients with radiologically isolated syndrome will develop MS. Some practitioners argue that these patients have a high likelihood of developing MS while others argue that up to two-thirds of these patients will not receive a diagnosis of MS in 5 years. A consensus panel decided to require clinical manifestations to make the diagnosis of MS (2017 McDonald Criteria for the diagnosis of Multiple Sclerosis).(21)		
	Clinical Presentation	Additional Data needed to make MS diagnosis	
	In a person with a typical a	ttack/CIS at onset	
	Greater than or equal to 2 attacks and objective clinical evidence of greater than or equal to 2 lesions OR Greater than or equal to 2 attacks and objective clinical evidence of 1 lesion with historical evidence of prior	None. Dissemination in space* and dissemination in time** have been met	

attack involving lesion in different location	
Greater than or equal to 2 attacks and objective clinical evidence of 1 lesion	ONE of these criteria: Additional clinical attack implicating different CNS site OR Greater than or equal to 1 symptomatic or asymptomatic MS-typical T2 lesions in greater than or equal to 2 areas of CNS: periventricular, juxtacortical/cortical, infratentorial, or spinal cord
1 attack and objective clinical evidence of greater than or equal to 2 lesions	ONE of these criteria: Additional clinical attack OR Simultaneous presence of both enhancing and non-enhancing symptomatic or asymptomatic MS- typical MRI lesions OR New T2 or enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan) OR CSF specific (i.e., not in serum) oligoclonal bands
1 attack and objective clinical evidence of 1 lesion	ONE of these criteria: Additional attack implicating different CNS site OR Greater than or equal to 1 MS-Typical symptomatic or asymptomatic T2 lesions in greater than or equal to 2 areas of CNS: periventricular, juxtacortical/cortical, infratentorial, or spinal cord AND ONE of these criteria: Additional clinical attack OR Simultaneous presence of both enhancing and non-enhancing symptomatic or asymptomatic MS- typical MRI lesions OR New T2 enhancing MRI lesion compared to baseline scan (without regard to timing of baseline scan) OR CSF-specific (i.e., not in serum) oligoclonal bands

^{*}Dissemination in space is defined as one or more T2-hyperintense lesions that are characteristic of multiple sclerosis in 2 or more of four areas of the CNS (periventricular, cortical or juxtacortical, and infratentorial brain regions, and the spinal cord) demonstrated by an additional clinical attack implicating a different CNS site or by MRI.(21)

^{**}Dissemination in time is defined as simultaneous presence of gadolinium-enhancing and non-enhancing lesions at any time or by a new T2-hyperintense or gadolinium-enhancing lesion on follow-up

MRI, with reference to a baseline scan, irrespective of the timing of the baseline MRI. The presence of CSF-specific oligoclonal bands does not demonstrate dissemination in time per se but can substitute for the requirement for demonstration of this measure.(21)

Treatment of MS

Both the Multiple Sclerosis Coalition and the American Academy of Neurology recommend initiating treatment with a DMA FDA approved for the patient's phenotype as soon as possible following the diagnosis of multiple sclerosis. There are several DMAs with at least 10 mechanisms of action available to people with MS. The factors affecting choice of therapy at any point in the disease course are complex and most appropriately analyzed and addressed through a shared decision-making process between the individual and the treating clinician.(16,19)

The Multiple Sclerosis Coalition recommends that clinicians should consider prescribing a high efficacy medication such as alemtuzumab, cladribine, fingolimod, natalizumab or ocrelizumab for newly diagnosed individuals with highly active MS. Clinicians should also consider prescribing a high efficacy medication for individuals who have breakthrough activity on another DMA regardless of the number of previously used agents.(16) The American Academy of Neurology has recommended alemtuzumab, fingolimod, and natalizumab as options for patients with MS with highly active MS. There lacks a consensus for what constitutes as highly active MS, however.(19) The National Institute for Health and Care Excellence (NICE) defines rapidly evolving severe RRMS as two or more disabling relapses in 1 year, and one or more gadolinium-enhancing lesions on brain MRI or a significant increase in T2 lesion load compared with a previous MRI.(31)

Lack of response to DMAs is hard to define, as most patients with MS are not free of all disease activity. Relapses or new MRI detected lesions may develop after initiation of a DMA and before the treatment becomes effective for patients. When determining efficacy, sufficient time for the DMA therapy to take full effect and patient adherence are important considerations. Evidence of one or more relapses, 2 or more unequivocally new MRI-detected lesions, or increased disability on examination while being treated with a DMA for a 1 year period suggests a sub-optimal response, an alternative regimen (e.g., different mechanism of action) should be considered to optimize therapeutic benefit.(18) A National MS Society consensus statement recommends changing from one disease modifying therapy to another only for medically appropriate reasons (e.g., lack of efficacy, adverse effects, or if better treatments options become available).(16)

Existing MS therapies are partly effective in halting ongoing inflammatory tissue damage and clinical progression. MS pathogenesis is complex and probably heterogeneous among patient, suggesting that combination therapy strategies that target a range of disease mechanisms might be more effective than medications used as monotherapy. Although preliminary studies have provided favorable results, however, several subsequent large, randomized, controlled trials have had negative of conflicting results. There also may be more adverse reactions associated with combination therapies due to the additive effect.(24)

In 2020 a Canadian MS working group published recommendations on optimal therapy in relapsing forms of MS. This group notes that there are few studies that have directly compared injectable and oral DMTs. A recent network meta-analysis suggested that pegylated interferon- β -1a and dimethyl fumarate have superior efficacy to other base therapies, there are insufficient data to demonstrate that one base injectable or oral DMT is superior to another. As a result, the choice of initial treatment will need to be individualized according to disease activity, severity, and comorbidities.(25)

In addition to base therapies, the working group considers 5 DMTs to be of higher efficacy which although can be used as initial therapy, they are generally reserved for patients with a poor response or tolerability with a base therapy. Patients presenting with high disease activity or aggressive/rapidly evolving MS at onset could be considered to initiate therapy with one of these more effective therapies, but the most common treatment initiation is to start on a base therapy with the view of switching within 6-12 months. The 5 agents considered to be of higher efficacy are:(25)

- Oral agents
 - Fingolimod
 - Cladribine
- Monoclonal antibodies
 - o Natalizumab
 - o Ocrelizumab
 - o Alemtuzumab

The MS working group discussed the criteria for switching therapies in RRMS and recommends a change in DMT is indicated for patients who meet any of the Major criteria below:(25)

	Minor	Major
Relapse rate	One relapse in first 2 years of treatment	 Greater than or equal to 2 relapses in first year of treatment
Severity	 Mild No functional impairment (school, work, daily activities, etc.) No motor/cerebel lar/brain stem /sphincter involvement 	 Moderate to severe Functional impairment Motor/cerebell ar/brain stem/sphincte r involvement
Recovery	 Full recovery at 6 months No functional impairment EDSS change from baseline less than or equal to 1 point at 6 months unless baseline EDSS greater than 5.5 	 Incomplete recovery Functional impairment If EDSS at baseline was 0 then greater than a 1.5 point change from baseline If EDSS greater than 0 but less than or equal to 5.5 at baseline then greater than 1 point change at 6 months If EDSS greater than 1 point change at 6 months If EDSS greater than 5.5 any change would

		be a major concern
MRI	One new lesion	 Greater than or equal to 3 new lesions during treatment excluding spinal cord lesions Greater than 1 spinal cord lesion

The workgroup does note that on-treatment relapses should only be performed once the drug has achieved a full clinical effect (typically 2-6 months after drug initiation). Relapses that occur before the maximal efficacy of the drug has been reached should be given less weight, but major criteria should take precedence regardless of timing.(25)

For patients with SPMS the workgroup states that is generally advised to continue with the current DMT after onset of SPMS since many patients will have ongoing inflammatory disease and subclinical disease activity may worsen if treatment is withdrawn. A change in treatment may be warranted in patients with active SPMS who continue to have relapses or new MRI lesions, with the caveat that there is insufficient evidence to identify criteria for a suboptimal response in patients with SPMS.(25)

For patients with primary progressive MS clinicians should offer ocrelizumab to patients with active disease provided the benefits outweigh the risks. Caution is recommended when considering treatment for PPMS subgroups that are less likely to benefit from treatment, such as older patients, those with long-standing stable disease, and/or significant neurological deficits, since the limited benefits may not justify the risk associated with treatment. Rituximab may be considered as an alternative therapy for PPMS in regions that permit off-label use in MS due to cost or other considerations.(25)

The Institute for Clinical and Economic Review (ICER) evaluated a new IV treatment, ublituximab against current FDA and accepted use DMT for adults with RRMS. Only in the case of ublituximab vs placebo/no DMT is ublituximab superior rated. The ratings are noted below.(17)

Adults with RRMS

Treatment	Comparator	Evidence Rating
	Natalizumab	I: Insufficient
	Ofatumumab	I: Insufficient
	Ocrelizumab	I: Insufficient
	Rituximab	I: Insufficient
Ublituximab	Fumarate class (dimethyl, diroximel, monomethyl)	C++: comparable or better
	Fingolimod	C++: comparable or better
	Ozanimod	C++: comparable or better
	Ponesimod	C++: comparable or better

		Siponimod	I: Insufficient
		Teriflunomide	B: Incremental
		Placebo/no DMT	A: Superior
	B: Incremental C++: Compara net health bene	- High certainty of a small net h ble or better - Moderate certainty	y of a comparable, small, or substantial ast a comparable net health benefit
	ICER does note	that payors should consider the	following:(17)
	appropr rituxima regardii other m • Payors	riate candidates for this therapy. ab with little or no prior authoriza ng use in appropriate patients ar nonoclonal antibodies of equal eff	nd how inexpensive it is compared with fectiveness at policies to switch RMS patients who
Safety	• Aubagi • Avone: • Bafiert • Betase • Copaxo • Extavia	liver injury, including acute liver reported in patients treated with setting. Concomitant use of Aub increase the risk of severe liver bilirubin levels within 6 months monitor ALT levels at least monitiver injury is suspected, discont elimination procedure Embryofetal toxicity: teratogenic animals administered teriflunominitiating Aubagio therapy. Advis females of reproductive potentia accelerated drug elimination propacted accelerated drug elimination propacted fective contraception. Aubagio Hypersensitivity reaction to terif inactive ingredients in Aubagio Coadministration with leflunomic (interferon β-1a) is contraindical History of hypersensitivity to na albumin or any other componentam (monomethyl fumarate) is contraindical fumarate, or any of the Co-administration with dimethyl seron (interferon β-1b) is contraindical History of hypersensitivity to na albumin or mannitol cone (glatiramer) is contraindicated Known hypersensitivity to glatira (interferon β-1b) is contraindicated (interfero	ant and potentially life-threatening failure requiring transplant, has been h Aubagio in the post marketing hagio with other hepatotoxic drugs may injury. Obtain transaminase and before initiation of Aubagio and thly for six months. If drug induced tinue Aubagio and start accelerated city and embryolethality occurred in hide. Exclude pregnancy prior to se use of effective contraception in hal during treatment and during an hocedure. Stop Aubagio and use an hocedure if the patient becomes ted in:(1) for reproductive potential not using hay cause fetal harm flunomide, leflunomide, or any of the de hated in:(2) htural or recombinant interferon beta, ht of the formulation hontraindicated in:(3) homethyl fumarate, dimethyl fumarate, he excipients of Bafiertam he fumarate or diroximel fumarate he dicated in:(4) htural or recombinant interferon beta, he dicated in:(5) hamer acetate or mannitol
		albumin (human), or mannitol a (fingolimod) is contraindicated	

- Recent myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure with hospitalization, or Class III/IV heart failure
- History of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker
- o Baseline QTc interval greater than or equal to 500 msec
- o Treatment with Class Ia or Class III anti-arrhythmic drugs
- Hypersensitivity to fingolimod or its excipients
- Glatopa (glatiramer) is contraindicated in:(8)
 - o Known hypersensitivity to glatiramer acetate or mannitol
- **Kesimpta** (ofatumumab) is contraindicated in:(9)
 - Active HBV infection
- Mavenclad (cladribine) contains a boxed warning with the following:(10)
 - Malignancies: Mavenclad may increase the risk of malignancy.
 Mavenclad is contraindicated in patients with current malignancy;
 evaluate the benefits and risks on an individual basis for patients with prior or increased risk of malignancy
 - Risk of teratogenicity: Mavenclad is contraindicated for use in pregnant women and in women and men of reproductive potential who do not plan to use effective contraception because of the risk of fetal harm
- Mavenclad (cladribine) is contraindicated in:(10)
 - Patients with current malignancy
 - Pregnant women, and women and men of reproductive potential who do not plan to use effective contraception during Mavenclad dosing and for 6 months after the last dose in each treatment course
 - HIV infection
 - o Active chronic infections (e.g., hepatitis or tuberculosis)
 - o History of hypersensitivity to cladribine
 - Women intending to breastfeed on a Mavenclad treatment day and for 10 days after the last dose
- Mayzent (siponimod) is contraindicated in:(11)
 - Patients with a CYP2C9 *3/*3 genotype
 - Patients who in the last 6 months have experienced: myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
 - Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
- **Plegridy** (peginterferon β-1a) is contraindicated in:(12)
 - History of hypersensitivity to natural or recombinant interferon beta or peginterferon, or any other component of Plegridy
- **Ponvory** (ponesimod) is contraindicated in:(27)
 - Patients who in the last 6 months experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure
 - Presence of Mobitz type II second-degree, third-degree AV block, or sick sinus syndrome, unless patient has a functioning pacemaker
- **Rebif** (interferon β-1a) is contraindicated in:(13)
 - History of hypersensitivity to natural or recombinant interferon beta, human albumin, or any other component of the formulation
- Tascenso ODT (fingolimod) is contraindicated in:(29)
 - Recent myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization or Class III/IV heart failure
 - History or presence of Mobitz Type II second-degree or third-degree AV block or sick sinus syndrome, unless patient has a functioning pacemaker
 - o Baseline QTc interval greater than or equal to 500 msec
 - Cardiac arrhythmias requiring anti-arrhythmic treatment with Class Ia or Class III anti-arrhythmic drugs
 - Hypersensitivity reaction to fingolimod or any of the excipients in Tascenso ODT. Observed reactions include rash, urticaria, and angioedema

- o Concomitant use with other products containing fingolimod
- **Tecfidera** (dimethyl fumarate) is contraindicated in:(14)
 - Known hypersensitivity to dimethyl fumarate or any of the excipients of Tecfidera
- **Vumerity** (diroximel fumarate) is contraindicated in:(15)
 - Known hypersensitivity to diroximel fumarate, dimethyl fumarate, or to any of the excipients of Vumerity
 - o Co-administration with dimethyl fumarate

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POLICY AGENT SUMMARY STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Availabl e MSC	Final Age Limit	Preferred Status
Non-Preferred Agents Excludin	g Copaxone, Glatopa, Tecfidera				•	
Vumerity	diroximel fumarate capsule delayed release	231 MG	M;N;O ;Y	N		2. Non- Preferred
	fingolimod hcl cap ; fingolimod lauryl sulfate tablet disintegrating	0.25 MG ; 0.5 MG	Υ	N;O;Y		
	teriflunomide tab	14 MG ; 7 MG	Υ	O ; Y		
Aubagio	teriflunomide tab	14 MG ; 7 MG	M;N;O	O ; Y		
Avonex; Avonex pen; Rebif; Rebif rebidose; Rebif rebidose titration; Rebif titration pack	interferon beta-	22 MCG/0.5ML ; 30 MCG/0.5ML; 44 MCG/0.5ML ; 6X8.8 & 6X22 MCG	M;N;O;Y	N		
Bafiertam	monomethyl fumarate capsule delayed release	95 MG	M;N;O;Y	N		
Betaseron	Interferon Beta- ; interferon beta-	0.3 MG	M;N;O;Y	N		
Copaxone	glatiramer acetate soln prefilled syringe	20 MG/ML ; 40 MG/ML	M;N;O	O ; Y		
Extavia	Interferon Beta- ; interferon beta-	0.3 MG	M;N;O;Y	N		
Gilenya	fingolimod hcl cap	0.25 MG ; 0.5 MG	M;N;O	N;O;Y		
Glatopa	glatiramer acetate soln prefilled syringe	20 MG/ML ; 40 MG/ML	Υ	O ; Y		
Kesimpta	ofatumumab soln auto-injector	20 MG/0.4ML	M;N;O;Y	N		
Mavenclad	cladribine tab therapy pack	10 MG	M;N;O;Y	N		
Mayzent ; Mayzent starter pack	siponimod fumarate tab	0.25 MG ; 1 MG ; 2 MG	M;N;O;Y	N		
Plegridy ; Plegridy starter pack	peginterferon beta-	125 MCG/0.5ML; 63 & 94 MCG/0.5ML	M;N;O ;Y	N		
Ponvory ; Ponvory 14-day starter pa	ponesimod tab ; ponesimod tab starter pack	2-3-4-5-6-7-8- 9 & 10 MG ; 20 MG	M;N;O ;Y	N		
Tascenso odt	fingolimod lauryl sulfate tablet disintegrating	0.25 MG ; 0.5 MG	M;N;O;Y	N		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Targeted MSC	Availabl e MSC	Final Age Limit	Preferred Status
Tecfidera ; Tecfidera starter pack	dimethyl fumarate capsule delayed release ; dimethyl fumarate capsule dr starter pack	120 & 240 MG ; 120 MG ; 240 MG	M;N;O	O; Y		
Vumerity	diroximel fumarate capsule delayed release	231 MG	M;N;O;Y	N		
	dimethyl fumarate capsule delayed release ; dimethyl fumarate capsule dr starter pack	120 & 240 MG ; 120 MG ; 240 MG	Y	O;Y		See Preferred Agents Detail

POLICY AGENT SUMMARY OUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strengt h	QL Amount	Dose Form	Day Supply	Duratio n	Addtl QL Info	Allowed Exceptions	Targete d NDCs When Exclusi ons Exist
	Diroximel Fumarate Capsule DR Starter Bottle 231 MG		106	Capsule s	180	DAYS			
Aubagio	teriflunomide tab	14 MG ; 7 MG	30	Tablets	30	DAYS			
Avonex	Interferon Beta-1a IM Prefilled Syringe Kit 30 MCG/0.5ML	30 MCG/0.5 ML	1	Kit	28	DAYS			
Avonex pen	Interferon Beta-1a IM Auto-Injector Kit 30 MCG/0.5ML	30 MCG/0.5 ML	1	Kit	28	DAYS			
Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	120	Capsule s	30	DAYS			
Betaseron	Interferon Beta- ; interferon beta-	0.3 MG	14	Vials	28	DAYS			504190 52401; 504190 52435
Copaxone ; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	30	Syringes	30	DAYS			
Copaxone ; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	12	Syringes	28	DAYS			
Extavia	Interferon Beta-; interferon beta-	0.3 MG	15	Vials	30	DAYS			000780 56912; 000780 56961; 000780 56999
Gilenya	fingolimod hcl cap	0.25 MG ; 0.5 MG	30	Capsule s	30	DAYS			
Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4 ML	1	Pen	28	DAYS			
Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	20	Tablets	301	DAYS			
Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	8	Tablets	301	DAYS			
Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	10	Tablets	301	DAYS			
Mavenclad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	12	Tablets	301	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strengt h	QL Amount	Dose Form	Day Supply	Duratio n	Addtl QL Info	Allowed Exceptions	Targete d NDCs When Exclusi ons Exist
Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	14	Tablets	301	DAYS			
Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	8	Tablets	301	DAYS			
Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	9	Tablets	301	DAYS			
Mayzent	Siponimod Fumarate Tab	1 MG	30	Tablets	30	DAYS			
Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	120	Tablets	30	DAYS			
Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	30	Tablets	30	DAYS			
Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	1	Pack	180	DAYS			
Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	1	Pack	180	DAYS			
Plegridy	Peginterferon Beta-	125 MCG/0.5 ML	2	Syringes	28	DAYS			
Plegridy	Peginterferon Beta- 1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5 ML	2	Pens	28	DAYS			
Plegridy	Peginterferon Beta- 1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5 ML	2	Syringes	28	DAYS			
Plegridy starter pack	Peginterferon Beta- 1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS			
Plegridy starter pack	Peginterferon Beta- 1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5 ML	1	Kit	180	DAYS			
Ponvory	Ponesimod Tab	20 MG	30	Tablets	30	DAYS			
Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5- 6-7-8-9 & 10 MG	1	Pack	180	DAYS			
Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS			
Rebif	Interferon Beta-1a Soln Pref Syr 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS			
Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5 ML	12	Syringes	28	DAYS			
Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5 ML	12	Syringes	28	DAYS			
Rebif rebidose titration	Interferon Beta-1a Auto-inj 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS			

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strengt h	QL Amount	Dose Form	Day Supply	Duratio n	Addtl QL Info	Allowed Exceptions	Targete d NDCs When Exclusi ons Exist
Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	1	Kit	180	DAYS			
Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.25 MG	30	Tablets	30	DAYS			
Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.5 MG	30	Tablets	30	DAYS			
Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	56	Capsule s	180	DAYS			
Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	60	Capsule s	30	DAYS			
Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	1	Kit	180	DAYS			
Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	120	Capsule s	30	DAYS			

CLIENT SUMMARY - STEP THERAPY

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary		
	fingolimod hcl cap ; fingolimod lauryl sulfate tablet disintegrating	0.25 MG ; 0.5 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
	teriflunomide tab	14 MG ; 7 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Aubagio	teriflunomide tab	14 MG ; 7 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Avonex; Avonex pen; Rebif; Rebif rebidose; Rebif rebidose titration; Rebif titration pack	interferon beta-	22 MCG/0.5ML; 30 MCG/0.5ML; 44 MCG/0.5ML; 6X8.8 & 6X22 MCG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Bafiertam	monomethyl fumarate capsule delayed release	95 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Betaseron	Interferon Beta- ; interferon beta-	0.3 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Copaxone	glatiramer acetate soln prefilled syringe	20 MG/ML ; 40 MG/ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Extavia	Interferon Beta- ; interferon beta-	0.3 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Gilenya	fingolimod hcl cap	0.25 MG ; 0.5 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Glatopa	glatiramer acetate soln prefilled syringe	20 MG/ML ; 40 MG/ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Kesimpta	ofatumumab soln auto-injector	20 MG/0.4ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	cladribine tab therapy pack	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mayzent ; Mayzent starter pack	siponimod fumarate tab	0.25 MG ; 1 MG ; 2 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Plegridy ; Plegridy starter pack	peginterferon beta-	125 MCG/0.5ML ; 63 & 94 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Ponvory ; Ponvory 14-day starter pa	ponesimod tab ; ponesimod tab starter pack	2-3-4-5-6-7-8-9 & 10 MG ; 20 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tascenso odt	fingolimod lauryl sulfate tablet disintegrating	0.25 MG ; 0.5 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tecfidera ; Tecfidera starter pack	dimethyl fumarate capsule delayed release ; dimethyl fumarate capsule dr starter pack	120 & 240 MG ; 120 MG ; 240 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Vumerity	diroximel fumarate capsule delayed release	231 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
	dimethyl fumarate capsule delayed release ; dimethyl fumarate capsule dr starter pack	120 & 240 MG; 120 MG; 240 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx

CLIENT SUMMARY - QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary		
	Diroximel Fumarate Capsule DR Starter Bottle 231 MG		FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Aubagio	teriflunomide tab	14 MG ; 7 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Avonex	Interferon Beta-1a IM Prefilled Syringe Kit 30 MCG/0.5ML	30 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Avonex pen	Interferon Beta-1a IM Auto-Injector Kit 30 MCG/0.5ML	30 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Bafiertam	Monomethyl Fumarate Capsule Delayed Release	95 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Betaseron	Interferon Beta- ; interferon beta-	0.3 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Copaxone ; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 20 MG/ML	20 MG/ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Copaxone ; Glatopa	Glatiramer Acetate Soln Prefilled Syringe 40 MG/ML	40 MG/ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Extavia	Interferon Beta- ; interferon beta-	0.3 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Gilenya	fingolimod hcl cap	0.25 MG ; 0.5 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx		
Kesimpta	Ofatumumab Soln Auto-Injector	20 MG/0.4ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open;		

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	Cladribine Tab Therapy Pack 10 MG (10 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	Cladribine Tab Therapy Pack 10 MG (4 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	Cladribine Tab Therapy Pack 10 MG (5 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenciad	Cladribine Tab Therapy Pack 10 MG (6 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	Cladribine Tab Therapy Pack 10 MG (7 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	Cladribine Tab Therapy Pack 10 MG (8 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mavenclad	Cladribine Tab Therapy Pack 10 MG (9 Tabs)	10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mayzent	Siponimod Fumarate Tab	1 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mayzent	Siponimod Fumarate Tab 0.25 MG (Base Equiv)	0.25 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mayzent	Siponimod Fumarate Tab 2 MG (Base Equiv)	2 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mayzent starter pack	Siponimod Fumarate Tab	0.25 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Mayzent starter pack	Siponimod Fumarate Tab 0.25 MG (12) Starter Pack	0.25 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
			Marketplace/BasicRx; KeyRx
Plegridy	Peginterferon Beta-	125 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Plegridy	Peginterferon Beta-1a Soln Pen-injector 125 MCG/0.5ML	125 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Plegridy	Peginterferon Beta-1a Soln Prefilled Syringe 125 MCG/0.5ML	125 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Plegridy starter pack	Peginterferon Beta-1a Soln Pen-inj 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Plegridy starter pack	Peginterferon Beta-1a Soln Pref Syr 63 & 94 MCG/0.5ML Pack	63 & 94 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Ponvory	Ponesimod Tab	20 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Ponvory 14-day starter pa	Ponesimod Tab Starter Pack	2-3-4-5-6-7-8-9 & 10 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Rebif	Interferon Beta-1a Soln Pref Syr 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Rebif	Interferon Beta-1a Soln Pref Syr 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Rebif rebidose	Interferon Beta-1a Soln Auto-Inj 22 MCG/0.5ML (12MU/ML)	22 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Rebif rebidose	Interferon Beta-1a Soln Auto-inj 44 MCG/0.5ML (24MU/ML)	44 MCG/0.5ML	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Rebif rebidose titration	Interferon Beta-1a Auto-inj 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Rebif titration pack	Interferon Beta-1a Pref Syr 6X8.8 MCG/0.2ML & 6X22 MCG/0.5ML	6X8.8 & 6X22 MCG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.25 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tascenso odt	Fingolimod Lauryl Sulfate Tablet Disintegrating	0.5 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tecfidera	Dimethyl Fumarate Capsule Delayed Release 120 MG	120 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tecfidera	Dimethyl Fumarate Capsule Delayed Release 240 MG	240 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Tecfidera starter pack	dimethyl fumarate capsule dr starter pack	120 & 240 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx
Vumerity	Diroximel Fumarate Capsule Delayed Release 231 MG	231 MG	FlexRx Closed; FlexRx Open; FocusRx; GenRx Closed; GenRx Open; Health Insurance Marketplace/BasicRx; KeyRx

PREFERRED AGENTS

STEP THERAPY CLINICAL CRITERIA FOR APPROVAL

Module		Clinical Criteri	a for Approval	
	TARGET AGENT(S)	TARGET AGENT(S)		
	Preferred generic agent(s)*	Preferred brand agent(s)	Nonpreferred agent(s)	
	dimethyl fumarate fingolimod glatiramer Glatopa (glatiramer) teriflunomide	Avonex (interferon beta-1a) Betaseron (interferon beta-1b) Kesimpta (ofatumumab) Mavenclad (cladribine) Mayzent (siponimod) Plegridy (peginterferon beta-1a) Rebif (interferon beta-1a) Vumerity (diroximel fumarate)	Aubagio (teriflunomide)* * Bafiertam (monomethyl fumarate) Copaxone (glatiramer)** Extavia (interferon beta-1b) Gilenya (fingolimod)** Ponvory (ponesimod) Tascenso ODT (fingolimod) Tecfidera (dimethyl fumarate)**	

Module	Clinical Criteria for Approval		
	* – These agents are subject to duplicate therapy check only ** – generic available		
	Target Agent(s) will be approved when ALL of the following are met:		
	1. ONE of following:		
	 A. The patient has been treated with the requested agent within the past 90 days OR B. The prescriber states the patient has been treated with the requested agent within the past 		
	90 days AND is at risk if therapy is changed OR		
	C. The patient is currently being treated with the requested agent as indicated by ALL of the following:		
	1. A statement by the prescriber that the patient is currently taking the requested		
	agent AND 2. A statement by the prescriber that the patient is currently receiving a positive		
	therapeutic outcome on requested agent AND		
	3. The prescriber states that a change in therapy is expected to be ineffective or caus		
	harm OR D. The requested agent is a preferred generic agent OR		
	E. The patient has highly active MS disease activity AND BOTH of the following:		
	 The patient has greater than or equal to 2 relapses in the previous year AND 		
	2. ONE of the following: A. The patient has greater than or equal to 1 gadolinium enhancing lesion on		
	MRI OR		
	 B. The patient has significant increase in T2 lesion load compared with a previous MRI OR 		
	F. The patient has been treated with at least 3 MS agents from different drug classes (see MS		
	disease modifying agents drug class table) OR		
	 G. The requested agent is a preferred brand agent AND ONE of the following: 1. The patient's medication history includes use of ONE preferred generic agent OR 		
	2. BOTH of the following:		
	A. The prescriber has stated that the patient has tried one preferred generic		
	agent AND B. The preferred generic agent was discontinued due to lack of effectiveness of the continued due to lack of the continued		
	an adverse event OR		
	 The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred 		
	generic agent OR		
	4. The patient has an FDA labeled contraindication to ALL preferred generic agents OI		
	The prescriber has provided documentation that ALL preferred generic agents cann be used due to a documented medical condition or comorbid condition that is likely		
	to cause an adverse reaction, decrease ability of the patient to achieve or maintain		
	reasonable functional ability in performing daily activities or cause physical or men		
	harm OR н. The requested agent is a nonpreferred agent AND ONE of the following:		
	1. The patient is 17 years of age or younger AND ONE of the following:		
	A. The requested agent does NOT have a corresponding preferred generic		
	strength OR B. The patient has tried and had an inadequate response to ONE preferred		
	generic agent FDA labeled for the patient's age for the requested indication		
	(medical records required) OR		
	 The patient has an intolerance (defined as an intolerance to drug or its excipients, not to the route of administration) or hypersensitivity to ONE 		
	preferred generic agent FDA labeled for the patient's age for the requested		
	indication OR		
	D. The patient has an FDA labeled contraindication to ALL preferred generic agents FDA labeled for the patient's age for the requested indication OR		
	E. The prescriber has provided documentation that ALL preferred generic		
	agents FDA labeled for the patient's age for the requested indication canno		
	be used due to a documented medical condition or comorbid condition that		

likely to cause an adverse reaction, decrease ability of the patient to achieve

or maintain reasonable functional ability in performing daily activities or
cause physical or mental harm OR
The patient is 19 years of ago or older AND ROTH of the following:

The patient is 18 years of age or older AND BOTH of the following:

Clinical Criteria for Approval

A. ONE of the following:

Module

- The patient's medication history incudes use of ONE preferred generic agent OR
- 2. BOTH of the following:
 - The prescriber has stated that the patient has tried one preferred generic agent AND
 - B. The preferred generic agent was discontinued due to lack of effectiveness or an adverse event **OR**
- 3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred generic agent **OR**
- The patient has an FDA labeled contraindication to ALL preferred generic agents OR
- 5. The prescriber has provided documentation that ALL preferred generic agents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
- B. ONE of the following:
 - The patient's medication history includes the use of ONE preferred brand agent or Zeposia (ozanimod) OR
 - 2. BOTH of the following:
 - A. The prescriber has stated that the patient has tried one preferred brand agent or Zeposia **AND**
 - B. The preferred brand agent or Zeposia was discontinued due to lack of effectiveness or an adverse event **OR**
 - 3. The patient has an intolerance (defined as an intolerance to the drug or its excipients, not to the route of administration) or hypersensitivity to ONE preferred brand agent or Zeposia **OR**
 - The patient has an FDA labeled contraindication to ALL preferred brand agents AND Zeposia OR
 - The prescriber has provided documentation that ALL preferred brand agents AND Zeposia cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND**
- 2. If the requested agent is a brand agent with a generic equivalent (listed below) AND ONE of the following:

Non-Preferred Agents	Corresponding generic equivalent
Aubagio	teriflunomide
Copaxone	Glatopa/glatiramer
Gilenya 0.5 mg	Fingolimod 0.5 mg
Tecfidera	dimethyl fumarate

- A. The patient's medication history includes use of the generic equivalent **OR**
- B. The patient is currently being treated with the requested agent as indicated by ALL of the following:
 - A statement by the prescriber that the patient is currently taking the requested agent AND
 - 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND**
 - The prescriber states that a change in therapy is expected to be ineffective or cause harm OR

Module	Clinical Criteria for Approval	
	C. The patient has an intolerance or hypersensitivity to the generic equivalent agent that is not expected to occur with the requested agent OR	
	D. The patient has an FDA labeled contraindication to the generic equivalent agent that is not expected to occur with the requested agent OR	
	 E. The prescriber has provided documentation that ALL generic equivalents cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm AND The patient will NOT be taking an additional disease modifying agent (DMA) for the requested indication 	
	Length of Approval: 12 months. NOTE: For agents requiring a starter dose for initial use, the starter dose will be approved for the FDA labeled starting dose and the maintenance dose will be approved for the remainder of 12 months.	
	NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.	

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval	
	Quantity Limit for Target Agent(s) will be approved when ONE of the following is met:	
	 The requested quantity (dose) does NOT exceed the program quantity limit OR The requested quantity (dose) exceeds the program quantity limit AND ONE of the following: BOTH of the following: The requested agent does not have a maximum FDA labeled dose for the requested indication AND There is support for therapy with a higher dose for the requested indication OR BOTH of the following: The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication AND There is support for why the requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does not exceed the program quantity limit OR BOTH of the following: The requested quantity (dose) exceeds the maximum FDA labeled dose for the requested indication AND There is support for therapy with a higher dose for the requested 	
	 There is support for therapy with a higher dose for the requested indication Length of Approval: up to 12 months NOTE: For agents requiring a starter dose for initial use, the starter dose can be approved for the FDA labeled starting dose and the maintenance dose can be approved for the remainder of 12 months 	

CLASS AGENTS

CEASS AGENTS	
Class	Class Drug Agents
Class Ia antiarrhythmics	
Class Ia antiarrhythmics	NORPACE*Disopyramide Phosphate Cap
Class Ia antiarrhythmics	Pronestyl (procainamide)
Class Ia antiarrhythmics	quinidine
Class III antiarrhythmics	
Class III antiarrhythmics	BETAPACE*Sotalol HCl Tab
Class III antiarrhythmics	Cordarone, Pacerone (amiodarone)
Class III antiarrhythmics	CORVERT*Ibutilide Fumarate Inj

Llass III antifarthythmics Tux (SSNP) Potentidade Cap (SD Disease Modifying Agents drug class: BRUMYI bilitizationab Sink profit (SSNP) Potentidade Cap (SD Disease Modifying Agents drug class: BRUMYI bilitizationab Sink profit (SSNP) Potentidade Cap (SD Disease Modifying Agents drug class: BRUMYI bilitizationab Sink profit (SSNP) Potentidade Cap (SD Disease Modifying Agents drug class: CDS2 monoclonal antibody (SD Disease Modifying Agents drug class: CDS2 monoclonal antibody (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus Soln For IV Infusion (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alentuzurus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: LEMTRADA*Alenturus IV Inj (SD Disease Modifying Agents drug class: Malenturus IV Inj (SD Disease Modifying Agents drug clas	Class	Class Drug Agents	
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MS Disease Modifying Agents drug class: ZEPOSIA*Ozanimod capsule Sphingosine 1-phosphate (SIP) receptor	MS Disease Modifying Agents Drug Class: Sphingosine 1-phosphate (SIP) receptor modulator	TASCENSO*fingolimod lauryl sulfate tablet disintegrating	
Sphingosine 1-phosphate (SIP) receptor	MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator		
	MS Disease Modifying Agents drug class: Sphingosine 1-phosphate (SIP) receptor modulator	ZEPOSIA*Ozanimod capsule	

CONTRAINDICATION AGENTS

Contraindicated as Concomitant Therapy

Examples of Contraindicated Concomitant Disease Modifying Agents (DMAs)

Aubagio (teriflunomide)*

Avonex (interferon β -1a)

Bafiertam (monomethyl fumarate)

Betaseron (interferon β -1b)

Briumvi (ublituximab-xiiy)

Copaxone (glatiramer)*

dimethyl fumarate

Extavia (interferon β-1b)

fingolimod

Gilenya (fingolimod)*

Glatopa (glatiramer)

glatiramer

Kesimpta (ofatumumab)

Lemtrada (alemtuzumab)

Mavenclad (cladribine)

Mayzent (siponimod)

Ocrevus (ocrelizumab)

Plegridy (peginterferon β -1a)

Ponvory (ponesimod)

Rebif (interferon β -1a)

Tascenso ODT (fingolimod)

Tecfidera (dimethyl fumarate)*

teriflunomide

Tysabri (natalizumab)

Vumerity (diroximel fumarate)

Zeposia (ozanimod)

* -generic available