

SPECIALTY QUANTITY LIMIT PROGRAM

Multiple Sclerosis Medications

I. PROGRAM DESCRIPTION

The standard limit is designed to allow a quantity sufficient for the most common uses of the medication. If the member's plan allows a quantity limit exception review for the requested medication, coverage of an additional quantity may be provided up to the exception limit with prior authorization

II. COVERED QUANTITIES

Medication	Standard Limit**	Exception Limit*	FDA-recommended dosing
Ampyra (dalfampridine) tablets 10mg	60 per 30 days	Not applicable	<ul style="list-style-type: none"> 10 mg orally twice daily
Aubagio (teriflunomide) tablets 7mg	30 per 30 days	Not applicable	<ul style="list-style-type: none"> 7 mg or 14 mg orally once daily
Aubagio (teriflunomide) tablets 14mg	30 per 30 days	Not applicable	
Avonex (interferon beta-1a) vial 30mcg	1 box (4 vials) per 28 days	Not applicable	
Avonex (interferon beta-1a) prefilled syringe 30mcg/0.5mL	1 box (4 syringes) per 28 days	Not applicable	<ul style="list-style-type: none"> The recommended dose is 30 mcg intramuscularly once weekly To reduce the incidence and severity of flu-like symptoms Avonex may be started at a dose of 7.5 mcg and the dose increased by 7.5 mcg each week for the next 3 weeks until the recommended dose of 30 mcg is achieved.
Avonex (interferon beta-1a) pen 30mcg/0.5mL	1 box (4 syringes) per 28 days	Not applicable	
Betaseron (interferon beta-1b) vial 0.3mg	14 per 28 days	Not applicable	
Copaxone (glatiramer acetate) prefilled syringe 20mg/mL	30 per 30 days	Not applicable	<ul style="list-style-type: none"> The recommended starting dose is 0.0625 mg (0.25 mL) subcutaneously every other day, with dose increases over a six-week period to the recommended dose of 0.25 mg (1 mL) every other day
Copaxone (glatiramer acetate) prefilled syringe 40mg/mL	12 per 28 days	Not applicable	<ul style="list-style-type: none"> 20 mg subcutaneously once daily
			<ul style="list-style-type: none"> 40 mg subcutaneously three times weekly and at least 48 hours apart

Medication	Standard Limit**	Exception Limit*	FDA-recommended dosing
Extavia (interferon beta-1b) vial 0.3mg	15 per 30 days	Not applicable	<ul style="list-style-type: none"> The recommended starting dose is 0.0625 mg (0.25 mL) subcutaneously every other day, with dose increases over a six-week period to the recommended dose of 0.25 mg (1 mL) every other day.
Glatopa (glatiramer acetate) prefilled syringe 20mg/mL	30 per 30 days	Not applicable	<ul style="list-style-type: none"> 20 mg subcutaneously once daily
Glatopa (glatiramer acetate) prefilled syringe 40mg/mL	12 per 28	Not applicable	<ul style="list-style-type: none"> 40 mg subcutaneously three times weekly and at least 48 hours apart
Gilenya (fingolomid) capsules 0.5mg	30 per 30 days	Not applicable	<ul style="list-style-type: none"> 0.5 mg orally once daily
Mavenclad (cladribine) tablets 10mg	20 per 9 months	Not applicable	<ul style="list-style-type: none"> 3.5mg/kg divided into two treatment courses (1.75mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles. Maximum recommended dose per cycle (110 kg and above): 100 mg
Mayzent (siponimod) 0.25mg tablets starter pack	12 per 5 days	Not applicable	<ul style="list-style-type: none"> Titration to reach 2 mg maintenance dosage: <ul style="list-style-type: none"> Day 1: 0.25mg Day 2: 0.25mg Day 3: 0.50mg Day 4: 0.75mg Day 5: 1.25mg Do not use the starter pack for patients who will be titrated to the 1-mg maintenance dosage
Mayzent (siponimod) 0.25mg tablets	112 per 28 days	Not applicable	<ul style="list-style-type: none"> Titration to reach 1 mg maintenance dosage: <ul style="list-style-type: none"> Day 1: 0.25mg Day 2: 0.25mg Day 3: 0.50mg Day 4: 0.75mg Day 5 and after: 1mg
Mayzent (siponimod) 2mg tablets	30 per 30 days	Not applicable	<ul style="list-style-type: none"> 2 mg daily after starter pack
Ocrevus vial 300mg/10mL	2 vials per 24 weeks	2 vials per 15 days	<p>Initial dose (two infusions):</p> <ul style="list-style-type: none"> Infusion 1: 300 mg Infusion 2 (2 weeks later): 300 mg <p>Subsequent doses: 600 mg (one infusion) every 6 months (1st subsequent dose is administered 6</p>

Medication	Standard Limit**	Exception Limit*	FDA-recommended dosing
			months after Infusion 1 of the initial dose)
Plegridy (peginterferon beta-1a) pen or prefilled syringe 125mcg/0.5mL	1 carton (2 pens or prefilled syringes) per 28 days	Not applicable	<ul style="list-style-type: none"> The recommended dose is 125 mcg subcutaneously every 14 days. Treatment initiation: <ul style="list-style-type: none"> Day 1: 63 mcg Day 15: 94 mcg Day 29 and every 14 days thereafter: 125 mcg (full dose)
Plegridy (peginterferon beta-1a) Starter Pack pen or prefilled syringe	1 Starter Pack (2 pens or prefilled syringes) per 28 days	Not applicable	
Rebif (interferon beta-1a) prefilled syringe or autoinjector 22mcg/0.5mL	12 (6 mL) per 28 days	Not applicable	<ul style="list-style-type: none"> The recommended dose is either 22 mcg or 44mcg subcutaneously three times weekly (at least 48 hours apart) Generally, patients should be started at 20% of the prescribed dose three times weekly and increased over a 4-week period to the targeted dose, either 22 mcg three times weekly or 44 mcg three times weekly. Titration schedule for a 22 mcg prescribed dose: <ul style="list-style-type: none"> Weeks 1 and 2 titration: 4.4mcg three times weekly Weeks 3 and 4 titration: 11mcg three times weekly Week 5 and after: 22 mcg three times weekly Titration schedule for a 44 mcg prescribed dose: <ul style="list-style-type: none"> Weeks 1 and 2 titration: 8.8mcg three times weekly Weeks 3 and 4 titration: 22mcg three times weekly Week 5 and after: 44 mcg three times weekly
Rebif (interferon beta-1a) prefilled syringe or autoinjector 44mcg/0.5mL	12 (6 mL) per 28 days	Not applicable	
Rebif (interferon beta-1a) titration pack w/ prefilled syringes or titration pack w/ autoinjectors)	12 (4.2 mL) per 28 days	Not applicable	
Tecfidera (dimethyl fumarate) capsules 120mg	14 per 28 days	56 per 84 days Temporary dose reductions are permitted once every 84 days	<ul style="list-style-type: none"> The starting dose is 120 mg orally twice a day. After 7 days, the dose should be increased to the maintenance dose of 240 mg orally twice daily. Temporary dose reductions to 120 mg twice daily may be considered for individuals who do not tolerate the maintenance dose. Within 4 weeks, the recommended dose of
Tecfidera (dimethyl fumarate) capsules 240mg	60 per 30 days	Not applicable	

Medication	Standard Limit**	Exception Limit*	FDA-recommended dosing
Tecfidera (dimethyl fumarate) 30-day Starter Pack	60 per 30 days	Not applicable	240 mg twice daily should be resumed.
Vumerity (diroximel fumarate) 30-day Starter dose bottle (bottle of 106 capsules) 231mg	106 per 30 days	Not applicable	<ul style="list-style-type: none"> The starting dosage for Vumerity is 231 mg twice a day orally. After 7 days, the dosage should be increased to the maintenance dosage of 462 mg (administered as two 231 mg capsules) twice a day orally. Temporary dosage reductions to 231 mg twice a day may be considered for individuals who do not tolerate the maintenance dosage. Within 4 weeks, the recommended dosage of 462 mg twice a day should be resumed.
Vumerity (diroximel fumarate) 30-day Maintenance dose bottle (bottle of 120 capsules) 231mg	120 per 30 days	Not applicable	
Zinbryta (daclizumab) prefilled syringe 150mg/mL	1 mL per 30 days	Not applicable	<ul style="list-style-type: none"> 150 mg subcutaneously once monthly

**The limit may apply to the generic equivalent medications

* Coverage up to the exception limits may be provided with prior authorization via the Specialty Post Limit Quantity Exception Criteria for approval.

III. REFERENCES

1. Ampyra [package insert]. Ardsley, NY: Acorda Therapeutics, Inc.; September 2017.
2. Aubagio [package insert]. Cambridge, MA: Genzyme Corporation; November 2016.
3. Avonex [package insert]. Cambridge, MA: Biogen Inc.; March 2016.
4. Betaseron [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; April 2016.
5. Copaxone [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; January 2018.
6. Extavia [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; May 2016.
7. Glatopa [package insert]. Princeton, NJ: Sandoz Inc.; January 2018.
8. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2017.
9. Mavenclad [package insert]. Rockland, MA: EMD Serono; March 2019.
10. Mayzent [package insert]. East Hanover, NJ: Novartis; March 2019.
11. Ocrevus [package insert]. South San Francisco, CA: Genentech, Inc.; March 2017.
12. Plegridy [package insert]. Cambridge, MA: Biogen Inc.; July 2016.
13. Rebif [package insert]. Rockland, MA: EMD Serono Inc.; November 2015.
14. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; December 2017.
15. Vumerity [package insert]. Cambridge, MA: Biogen; October 2019.
16. Zinbryta [package insert]. Cambridge, MA: Biogen Inc.; August 2017.