

## 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"> <li>10 mg orally twice daily</li> </ul>
Aubagio (teriflunomide) tablets 7mg	30 per 30 days	Not applicable	<ul style="list-style-type: none"> <li>7 mg or 14 mg orally once daily</li> </ul>
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"> <li>The recommended dose is 30 mcg intramuscularly once weekly</li> <li>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.</li> </ul>
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"> <li>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</li> </ul>
Copaxone (glatiramer acetate) prefilled syringe 40mg/mL	12 per 28 days	Not applicable	<ul style="list-style-type: none"> <li>20 mg subcutaneously once daily</li> </ul>
			<ul style="list-style-type: none"> <li>40 mg subcutaneously three times weekly and at least 48 hours apart</li> </ul>

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"> <li>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.</li> </ul>
Glatopa (glatiramer acetate) prefilled syringe 20mg/mL	30 per 30 days	Not applicable	<ul style="list-style-type: none"> <li>20 mg subcutaneously once daily</li> </ul>
Glatopa (glatiramer acetate) prefilled syringe 40mg/mL	12 per 28	Not applicable	<ul style="list-style-type: none"> <li>40 mg subcutaneously three times weekly and at least 48 hours apart</li> </ul>
Gilenya (fingolomid) capsules 0.5mg	30 per 30 days	Not applicable	<ul style="list-style-type: none"> <li>0.5 mg orally once daily</li> </ul>
Mavenclad (cladribine) tablets 10mg	20 per 9 months	Not applicable	<ul style="list-style-type: none"> <li>3.5mg/kg divided into two treatment courses (1.75mg/kg per treatment course). Each treatment course is divided into 2 treatment cycles.</li> <li>Maximum recommended dose per cycle (110 kg and above): 100 mg</li> </ul>
Mayzent (siponimod) 0.25mg tablets starter pack	12 per 5 days	Not applicable	<ul style="list-style-type: none"> <li>Titration to reach 2 mg maintenance dosage: <ul style="list-style-type: none"> <li>Day 1: 0.25mg</li> <li>Day 2: 0.25mg</li> <li>Day 3: 0.50mg</li> <li>Day 4: 0.75mg</li> <li>Day 5: 1.25mg</li> </ul> </li> <li>Do not use the starter pack for patients who will be titrated to the 1-mg maintenance dosage</li> </ul>
Mayzent (siponimod) 0.25mg tablets	112 per 28 days	Not applicable	<ul style="list-style-type: none"> <li>Titration to reach 1 mg maintenance dosage: <ul style="list-style-type: none"> <li>Day 1: 0.25mg</li> <li>Day 2: 0.25mg</li> <li>Day 3: 0.50mg</li> <li>Day 4: 0.75mg</li> <li>Day 5 and after: 1mg</li> </ul> </li> </ul>
Mayzent (siponimod) 2mg tablets	30 per 30 days	Not applicable	<ul style="list-style-type: none"> <li>2 mg daily after starter pack</li> </ul>
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"> <li>Infusion 1: 300 mg</li> <li>Infusion 2 (2 weeks later): 300 mg</li> </ul> <p>Subsequent doses: 600 mg (one infusion) every 6 months (1<sup>st</sup> 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"> <li>The recommended dose is 125 mcg subcutaneously every 14 days.</li> <li>Treatment initiation: <ul style="list-style-type: none"> <li>Day 1: 63 mcg</li> <li>Day 15: 94 mcg</li> <li>Day 29 and every 14 days thereafter: 125 mcg (full dose)</li> </ul> </li> </ul>
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"> <li>The recommended dose is either 22 mcg or 44mcg subcutaneously three times weekly (at least 48 hours apart)</li> <li>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.</li> <li>Titration schedule for a 22 mcg prescribed dose: <ul style="list-style-type: none"> <li>Weeks 1 and 2 titration: 4.4mcg three times weekly</li> <li>Weeks 3 and 4 titration: 11mcg three times weekly</li> <li>Week 5 and after: 22 mcg three times weekly</li> </ul> </li> <li>Titration schedule for a 44 mcg prescribed dose: <ul style="list-style-type: none"> <li>Weeks 1 and 2 titration: 8.8mcg three times weekly</li> <li>Weeks 3 and 4 titration: 22mcg three times weekly</li> <li>Week 5 and after: 44 mcg three times weekly</li> </ul> </li> </ul>
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"> <li>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.</li> <li>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</li> </ul>
Tecfidera (dimethyl fumarate) capsules 240mg	60 per 30 days	Not applicable	

<b>Reference number(s)</b>
1798-H

<b>Medication</b>	<b>Standard Limit**</b>	<b>Exception Limit*</b>	<b>FDA-recommended dosing</b>
Tecfidera (dimethyl fumarate) 30-day Starter Pack	60 per 30 days	Not applicable	240 mg twice daily should be resumed.
Zinbryta (daclizumab) prefilled syringe 150mg/mL	1 mL per 30 days	Not applicable	<ul style="list-style-type: none"> <li>150 mg subcutaneously once monthly</li> </ul>

\*\* 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.
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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.
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8. Gilenya [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2017.
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13. Rebif [package insert]. Rockland, MA: EMD Serono Inc.; November 2015.
14. Tecfidera [package insert]. Cambridge, MA: Biogen Inc.; December 2017.
15. Zinbryta [package insert]. Cambridge, MA: Biogen Inc.; August 2017.
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