

Efgartigimod (Vyvgart™)

Goal(s):

- Restrict use to OHP-funded conditions.
- Promote use that is consistent with medical evidence.

Length of Authorization:

Up to 12 months

Requires PA:

- Vyvgart™ (efgartigimod) pharmacy and physician administered claims.

Covered Alternatives:

- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this an FDA approved indication?	Yes: Go to #3	No: Pass to RPh. Deny; medical appropriateness
3. Is this a request for continuation of therapy?	Yes: Go to Renewal Criteria	No: Go to #4
4. Is the diagnosis funded by OHP?	Yes: Go to #5	No: Pass to RPh. Deny; not funded by the OHP.
5. Is the request for efgartigimod made by, or in consultation with, a neurologist or rheumatologist?	Yes: Go to #6	No: Pass to RPh. Deny; medical appropriateness
6. Does the patient have an active infection?	Yes: Pass to RPh. Deny; medical appropriateness.	No: Go to #7

Approval Criteria

<p>7. Has the patient received, or have contraindications to, all routine immunizations recommended for their age?</p> <p>Note: Routine vaccinations for patients at least 2 years of age typically included hepatitis B, hepatitis A, diphtheria, tetanus, pertussis, pneumococcal conjugate, inactivated poliovirus, influenza, and at least 2 doses of measles, mumps, rubella, and varicella. Immunization with live-attenuated or live vaccines is not recommended during efgartigimod treatment.</p>	<p>Yes: Go to #8.</p> <p>Document physician attestation of immunization history</p>	<p>No: Pass to RPh. Deny; medical appropriateness. Administer vaccines before initiation of a new treatment cycle of efgartigimod</p>
<p>8. Does the patient have a positive serological test for anti-AChR antibodies?</p>	<p>Yes: Go to #9</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>9. Does the patient have a Myasthenia Gravis Foundation of America (MGFA) Clinical Classification of class II, III or IV?</p>	<p>Yes: Go to #10</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>10. Does the patient have a myasthenia gravis-specific activities of daily living scale (MG-ADL) total score of 5 points or more?</p>	<p>Yes: Go to #11</p> <p>Record baseline MG-ADL score</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>11. Has the patient received or is currently receiving two immunosuppressant therapies (as monotherapy or in combination) for at least one year without adequate symptom control or do they have contraindications to these therapies?</p> <p>Example immunosuppressant therapies:</p> <ul style="list-style-type: none"> - Azathioprine - Cyclosporine - Mycophenolate mofetil - Tacrolimus - Methotrexate - Cyclophosphamide 	<p>Yes: Go to #12</p>	<p>No: Pass to RPh. Deny; medical appropriateness. Recommend trial of immunosuppressant therapy</p>

Approval Criteria

<p>12. Is the request for efgartigimod dosing that corresponds to FDA labeling?</p> <ul style="list-style-type: none"> • 10 mg/kg once weekly for 4 weeks • For patients weighing 120 kg or more, the recommended dose is 1200 mg per infusion 	<p>Yes: Approve for up to two cycles. Each cycle is 1 dose/week for 4 weeks. The second cycle should not be administered sooner than 50 days from start of previous cycle.</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
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Renewal Criteria

<p>1. Has it been 50 days or more from the start of the previous efgartigimod treatment cycle?</p>	<p>Yes: Go to #2</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>2. Is this request for the first renewal of efgartigimod?</p>	<p>Yes: Go to #3</p>	<p>No: Go to #4</p>
<p>3. Has the patient experienced a reduction in symptoms of at least 2 points from MG-ADL total baseline score?</p>	<p>Yes: Approve for up to 5 cycles. Each cycle is 1 dose/week for 4 weeks. Additional cycles should not be administered sooner than 50 days from start of previous cycle.</p> <p>Record MG-ADL score</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>
<p>4. Has the patient maintained a stable MG-ADL score over the last 12 months of efgartigimod therapy?</p>	<p>Yes: Approve for up to 7 cycles. Each cycle is 1 dose/week for 4 weeks. Additional cycles should not be administered sooner than 50 days from start of previous cycle.</p> <p>Record MG-ADL score</p>	<p>No: Pass to RPh. Deny; medical appropriateness</p>