

NEONATAL FC RECEPTOR (FCRN) ANTAGONISTS



Included Products: Rystiggo (rozanolixizumab-noli), Vyvgart (efgartigimod alfa-fcab), Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)

Created: 07/11/2024 Revised: 09/12/2024 Reviewed: 09/12/2024 Updated: 10/01/2024

Nonformulary for outpatient benefit. PA required on medical benefit.

Myasthenia Gravis			
Initial Criteria		If yes	If no
1.	Is the drug prescribed by or in consultation with neurologist?	Continue to #2.	Do not approve.
2.	Does the member have generalized myasthenia gravis with clinical classification II to IV?	Continue to #3.	Continue to #6.
3.	Is there documentation which confirms the diagnosis is anti-acetylcholine receptor (AChR) antibody positive?	Continue to #6.	Continue to #4.
4.	Is the request for Rystiggo?	Continue to #5.	Do not approve.
5.	Is there documentation which confirms the diagnosis is anti-muscle-specific tyrosine kinase (MuSK) antibody positive?	Continue to #6.	Do not approve.
6.	Has a baseline MG Activities of Daily Living (MG-ADL) score been obtained?	Continue to #7.	Do not approve.
7.	Has the member tried and failed ALL of the following? <ul style="list-style-type: none"> a. Pyridostigmine; AND b. Corticosteroids; AND c. At least two immune modulating agents including azathioprine, mycophenolate, cyclosporine, and tacrolimus; AND d. IVIG 	Continue to #8.	Do not approve.
8.	Has the case's medical necessity been confirmed with external specialist and medical director review?	Continue to #9.	Have these activities completed.
9.	Approve for 6 months.		
Renewal Criteria		If yes	If no
1.	Is there documentation which demonstrates a	Continue to #2.	Do not approve.

	clinically significant and meaningful response to therapy?		
2.	Review with medical director.	Continue to #3.	Do not approve.
3.	Approve for 6 months.		

Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)

Initial Criteria		If yes	If no
1.	Is the drug prescribed by or in consultation with neurologist?	Continue to #2.	Do not approve.
2.	Is the drug indicated or supported for treating CIDP?	Continue to #3.	Do not approve.
3.	Has the condition persisted for longer than 2 months?	Continue to #4.	Do not approve.
4.	Is there documentation of a baseline strength and weakness using an objective clinical measuring tool, such as Inflammatory Neuropathy Cause and Treatment Score (INCAT), Medical Research Council (MRC), 6-minute timed walking test, Rankin, or Modified Rankin?	Continue to #4.	Do not approve.
5.	Has the diagnosis been made on the basis of electrophysiologic findings that support the diagnosis and rule out other possible conditions that may not respond to Vyvgart treatment?	Continue to #5.	Do not approve.
6.	Has the member failed, or have contraindications to, both of the following to treat chronic inflammatory demyelinating polyneuropathy? a. Corticosteroids b. IVIG	Continue to #7.	Do not approve.
7.	Approve for 3 months.		
Renewal Criteria		If yes	If no
1.	Has the member displayed an improvement from baseline strength and weakness using an objective clinical measuring tool?	Continue to #2.	Do not approve.
2.	Approve for 6 months.		