Anti-Alpha-4-Integrin Antibodies

Included Products: Entyvio (vedolizumab), Tysabri (natalizumab)

Nonformulary for outpatient benefit. PA required on medical benefit.

Created: 11/14/2019 *Revised:* 03/10/2022 *Reviewed:* 01/12/2023 *Updated:* 02/01/2023

All Diagnoses

Initial Criteria		If yes	If no
1.	Is the requested agent indicated for or supported for use in the submitted diagnosis for the member's age?	Continue to #2.	Do not approve.
2.	Is the request for maintenance of remission in a patient who already achieved remission with the requested product or has already initiated therapy?	Continue to renewal criteria for the submitted diagnosis.	Continue to #3.
3.	Has the treatment been initiated by or is an appropriate specialist currently supervising it? a. Crohn's Disease: Gastroenterologist b. Multiple Sclerosis: Neurologist c. Ulcerative Colitis: Gastroenterologist	Continue to #4.	Do not approve.
4.	Is the requested agent to be used in combination with another biologic?	Do not approve.	Continue to diagnosis.

Crohn's Disease

Initial Criteria		If yes	If no
1.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #3	Continue to #2.
2.	Does the member have moderate to severe Crohn's disease?	Continue to #3.	Do not approve.

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3.	Has the member failed at least TWO TNF inhibitors or have contraindications to all TNF inhibitors?	Continue to #4.	Do not approve.
4.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
1.	Has the member experienced a decrease in symptoms, reduction in enterocutaneous fistulas or clinical remission?	Continue to #2.	Do not approve.
2.	Approve 12 months.		

Multiple Sclerosis

Initial Criteria		**If yes**	**If no**
1.	Does the member have a diagnosis of relapsing-remitting multiple sclerosis?	Continue to #2.	Do not approve.
2.	Is monotherapy intended with the requested product?	Continue to #3.	Do not approve.
3.	Has the member failed (continuation of clinical relapses, CNS lesion progression on MRI, or worsening disability) while adherent to therapy on, or have contraindications to dimethyl fumarate?	Continue to #4.	Do not approve.
4.	Approve for 12 months		
Renewal Criteria		**If yes**	**If no**
1.	Is there documentation of benefit since initiation, such as delay in the accumulation of physical disability and/or reduction in the frequency of clinical exacerbations and no symptoms suggestive of PML?	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

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Ulcerative Colitis

Initial Criteria		If yes	If no
1.	Is the member transitioning to the requested treatment from a different biologic product?	Continue to #3.	Continue to #2.
2.	Does the member have a diagnosis of moderate to severe ulcerative colitis defined by the following criteria: a. Moderate = greater than or equal to 4 stools daily. b. Severe = greater than or equal to 6 bloody stools daily and evidence of toxicity such as fever, anemia, elevated ESR, or tachycardia.	Continue to #2.	Do not approve.
3.	Has the member failed at least TWO TNF inhibitors or have contraindications to all TNF inhibitors?	Continue to #4.	Do not approve.
4.	Approve for 6 months.		
Renewal Criteria		**If yes**	**If no**
1.	Has the member demonstrated a significant response including the following: a. Decrease in bloody stools per day and/or b. Elimination of signs of toxicity.	Continue to #2.	Do not approve.
2.	Approve for 12 months.		

REFERENCES

- ACG Clinical Guideline: Management of Crohn's Disease in Adults (2018)
- ACG Clinical Guideline: Ulcerative Colitis in Adults (2019)