Subject: **Vedolizumab (Entyvio®)**

Effective Date: **April 17, 2018**

Department(s): **Utilization Management**

Policy: Vedolizumab (Entyvio) (**HCPCS J3380**), a humanized monoclonal antibody that blocks T-cell adhesion molecule (integrin) function inhibiting migration into inflamed gastrointestinal tissue, is reimbursable under Plans administered by QualCare, Inc. under the circumstances enumerated in this Policy.

Objective: To assure proper and consistent reimbursement and to delineate criteria for coverage of a specific therapeutic agent.

Procedure:

A. For use in treating adults with moderately to severely active Crohn disease (**ICD-10 K50.00-K50.919)** when there is failure or inadequate response, contraindication per FDA label, or documented intolerance to at least ONE anti-tumor necrosis factor therapy (adalimumab[Humira], infliximab[Remicade], or certolizumab [Cimzia]).

B. For use in treating adults with moderately to severely active ulcerative colitis (**ICD-10 K51.0-K51.39**) when there is failure or inadequate response, contraindication per FDA label, or documented intolerance to at least ONE conventional therapy (i.e., aminosalicylate, corticosteroids, or

immumomodulators such as azathioprine, 6-mercaptopurine)

AND

failure or inadequate response, contraindication per FDA label, or documented intolerance to at least ONE anti-tumor necrosis factor therapy (adalimumab[Humira], infliximab[Remicade], or golimumab[Simponi]).

Initial authorization when the above criteria are met is for four months. Subsequent annual authorization is approvable with documented initial and continued clinical response.

FDA recommended dosing in Crohn's disease and Ulcerative colitis:
300 mg administered by intravenous infusion at zero, two and six weeks and then every eight weeks thereafter. Discontinue therapy in patients who show no evidence of therapeutic benefit by Week 14.

References

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*Consistent with Summary Plan Description (SPD). If there is discordance with the SPD, provisions of the SPD take precedence.