

**Texas Prior Authorization Program
Clinical Criteria**

Drug/Drug Class**Cytokine and CAM Antagonists**

This criteria was recommended for review by the Texas Medicaid Vendor Drug Program to ensure appropriate and safe utilization

Clinical Criteria Information Included in this Document**Entyvio SC (vedolizumab)**

- **Drugs requiring prior authorization:** the list of drugs requiring prior authorization for this clinical criteria
- **Prior authorization criteria logic:** a description of how the prior authorization request will be evaluated against the clinical criteria rules
- **Logic diagram:** a visual depiction of the clinical criteria logic
- **Supporting tables:** a collection of information associated with the steps within the criteria (diagnosis codes, procedure codes, and therapy codes)
- **References:** clinical publications and sources relevant to this clinical criteria

Note: Click the hyperlink to navigate directly to that section.

Revision Notes

Initial publication and presentation to DUR Board



Entyvio SC (vedolizumab)

Drugs Requiring Prior Authorization

Entyvio SC	
Label Name	GCN
ENTYVIO 108 MG/0.68 ML PEN	48647



Entyvio SC (vedolizumab)

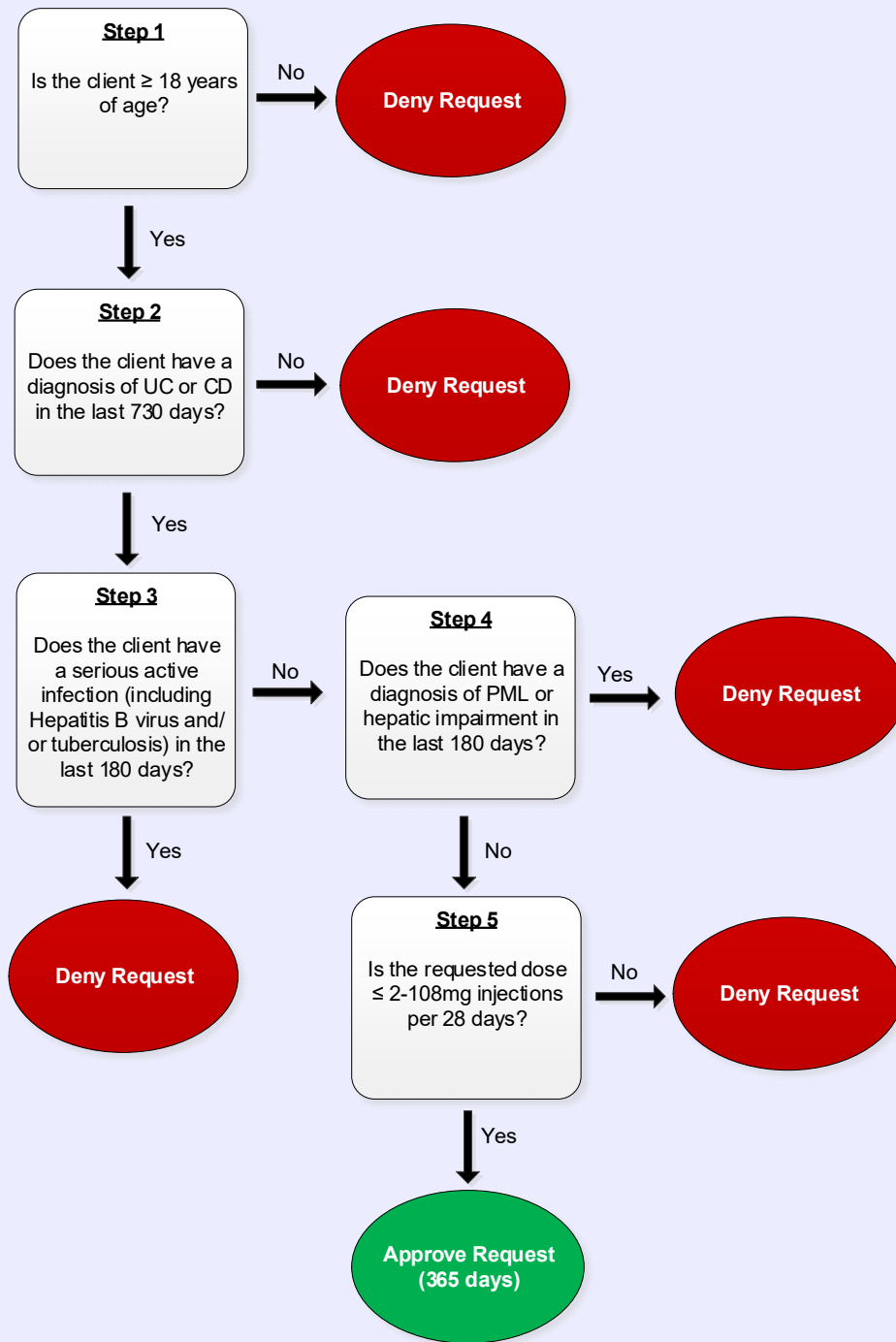
Clinical Criteria Logic

1. Is the client greater than or equal to (\geq) 18 years of age?
 Yes – Go to #2
 No – Deny
2. Does the client have a diagnosis of **ulcerative colitis or Crohn’s disease** in the last 730 days?
 Yes – Go to #3
 No – Deny
3. Does the client have a **serious active infection** (including Hepatitis B virus and/or tuberculosis) in the last 180 days?
 Yes – Deny
 No – Go to #4
4. Does the client have a **diagnosis of progressive multifocal leukoencephalopathy (PML) or hepatic impairment** in the last 180 days?
 Yes – Deny
 No – Go to #5
5. Is the requested dose less than or equal to (\leq) 2-108mg injections per 28 days?
 Yes – Approve (365 days)
 No – Deny



Entyvio SC (vedolizumab)

Clinical Criteria Logic Diagram





Entyvio SC (vedolizumab)

Clinical Criteria Supporting Tables

Step 2 (diagnosis of ulcerative colitis or Crohn's disease)	
Required quantity: 1	
Look back timeframe: 730 days	
ICD-10 Code	Description
K5100	ULCERATIVE (CHRONIC) PANCOLITIS WITHOUT COMPLICATIONS
K51011	ULCERATIVE (CHRONIC) PANCOLITIS WITH RECTAL BLEEDING
K51012	ULCERATIVE (CHRONIC) PANCOLITIS WITH INTESTINAL OBSTRUCTION
K51013	ULCERATIVE (CHRONIC) PANCOLITIS WITH FISTULA
K51014	ULCERATIVE (CHRONIC) PANCOLITIS WITH ABSCESS
K51018	ULCERATIVE (CHRONIC) PANCOLITIS WITH OTHER COMPLICATION
K51019	ULCERATIVE (CHRONIC) PANCOLITIS WITH UNSPECIFIED COMPLICATIONS
K5120	ULCERATIVE (CHRONIC) PROCTITIS WITHOUT COMPLICATIONS
K51211	ULCERATIVE (CHRONIC) PROCTITIS WITH RECTAL BLEEDING
K51212	ULCERATIVE (CHRONIC) PROCTITIS WITH INTESTINAL OBSTRUCTION
K51213	ULCERATIVE (CHRONIC) PROCTITIS WITH FISTULA
K51214	ULCERATIVE (CHRONIC) PROCTITIS WITH ABSCESS
K51218	ULCERATIVE (CHRONIC) PROCTITIS WITH OTHER COMPLICATION
K51219	ULCERATIVE (CHRONIC) PROCTITIS WITH UNSPECIFIED COMPLICATIONS
K5130	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITHOUT COMPLICATIONS
K51311	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITH RECTAL BLEEDING
K51312	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITH INTESTINAL OBSTRUCTION
K51313	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITH FISTULA
K51314	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITH ABSCESS
K51318	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITH OTHER COMPLICATION
K51319	ULCERATIVE (CHRONIC) RECTOSIGMOIDITIS WITH UNSPECIFIED COMPLICATIONS
K5180	OTHER ULCERATIVE COLITIS WITHOUT COMPLICATIONS
K51811	OTHER ULCERATIVE COLITIS WITH RECTAL BLEEDING
K51812	OTHER ULCERATIVE COLITIS WITH INTESTINAL OBSTRUCTION
K51813	OTHER ULCERATIVE COLITIS WITH FISTULA
K51814	OTHER ULCERATIVE COLITIS WITH ABSCESS

Step 2 (diagnosis of ulcerative colitis or Crohn's disease)	
Required quantity: 1	
Look back timeframe: 730 days	
K51818	OTHER ULCERATIVE COLITIS WITH OTHER COMPLICATION
K51819	OTHER ULCERATIVE COLITIS WITH UNSPECIFIED COMPLICATIONS
K5190	ULCERATIVE COLITIS, UNSPECIFIED WITHOUT COMPLICATIONS
K51911	ULCERATIVE COLITIS, UNSPECIFIED WITH RECTAL BLEEDING
K51912	ULCERATIVE COLITIS, UNSPECIFIED WITH INTESTINAL OBSTRUCTION
K51913	ULCERATIVE COLITIS, UNSPECIFIED WITH FISTULA
K51914	ULCERATIVE COLITIS, UNSPECIFIED WITH ABSCESS
K51918	ULCERATIVE COLITIS, UNSPECIFIED WITH OTHER COMPLICATION
K51919	ULCERATIVE COLITIS, UNSPECIFIED WITH UNSPECIFIED COMPLICATIONS
K5000	CROHN'S DISEASE OF SMALL INTESTINE WITHOUT COMPLICATIONS
K50011	CROHN'S DISEASE OF SMALL INTESTINE WITH RECTAL BLEEDING
K50012	CROHN'S DISEASE OF SMALL INTESTINE WITH INTESTINAL OBSTRUCTION
K50013	CROHN'S DISEASE OF SMALL INTESTINE WITH FISTULA
K50014	CROHN'S DISEASE OF SMALL INTESTINE WITH ABSCESS
K50018	CROHN'S DISEASE OF SMALL INTESTINE WITH OTHER COMPLICATION
K50019	CROHN'S DISEASE OF SMALL INTESTINE WITH UNSPECIFIED COMPLICATIONS
K5010	CROHN'S DISEASE OF LARGE INTESTINE WITHOUT COMPLICATIONS
K50111	CROHN'S DISEASE OF LARGE INTESTINE WITH RECTAL BLEEDING
K50112	CROHN'S DISEASE OF LARGE INTESTINE WITH INTESTINAL OBSTRUCTION
K50113	CROHN'S DISEASE OF LARGE INTESTINE WITH FISTULA
K50114	CROHN'S DISEASE OF LARGE INTESTINE WITH ABSCESS
K50118	CROHN'S DISEASE OF LARGE INTESTINE WITH OTHER COMPLICATION
K50119	CROHN'S DISEASE OF LARGE INTESTINE WITH UNSPECIFIED COMPLICATIONS
K5080	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITHOUT COMPLICATIONS
K50811	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITH RECTAL BLEEDING
K50812	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITH INTESTINAL OBSTRUCTION
K50813	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITH FISTULA
K50814	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITH ABSCESS
K50818	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITH OTHER COMPLICATION

Step 2 (diagnosis of ulcerative colitis or Crohn's disease)	
Required quantity: 1	
Look back timeframe: 730 days	
K50819	CROHN'S DISEASE OF BOTH SMALL AND LARGE INTESTINE WITH UNSPECIFIED COMPLICATIONS
K5090	CROHN'S DISEASE, UNSPECIFIED WITHOUT COMPLICATIONS
K50911	CROHN'S DISEASE, UNSPECIFIED, WITH RECTAL BLEEDING
K50912	CROHN'S DISEASE, UNSPECIFIED, WITH INTESTINAL OBSTRUCTION
K50913	CROHN'S DISEASE, UNSPECIFIED, WITH FISTULA
K50914	CROHN'S DISEASE, UNSPECIFIED, WITH ABSCESS
K50918	CROHN'S DISEASE, UNSPECIFIED, WITH OTHER COMPLICATION
K50919	CROHN'S DISEASE, UNSPECIFIED, WITH UNSPECIFIED COMPLICATIONS

Step 3 (serious active infection)	
Required quantity: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
A150	TUBERCULOSIS OF LUNG
A154	TUBERCULOSIS OF INTRATHORACIC LYMPH NODES
A155	TUBERCULOSIS OF LARYNX, TRACHEA AND BRONCHUS
A156	TUBERCULOUS PLEURISY
A157	PRIMARY RESPIRATORY TUBERCULOSIS
A158	OTHER RESPIRATORY TUBERCULOSIS
A159	RESPIRATORY TUBERCULOSIS UNSPECIFIED
B440	INVASIVE PULMONARY ASPERGILLOSIS
B441	OTHER PULMONARY ASPERGILLOSIS
B447	DISSEMINATED ASPERGILLOSIS
B449	ASPERGILLOSIS, UNSPECIFIED
B59	PNEUMOCYSTOSIS

Step 4 (diagnosis of PML or hepatic impairment)	
Required quantity: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
A812	PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY
B160	ACUTE HEPATITIS B WITH DELTA-AGENT WITH HEPATIC COMA
B161	ACUTE HEPATITIS B WITH DELTA-AGENT WITHOUT HEPATIC COMA
B162	ACUTE HEPATITIS B WITHOUT DELTA-AGENT WITH HEPATIC COMA
B169	ACUTE HEPATITIS B WITHOUT DELTA-AGENT AND WITHOUT HEPATIC COMA
B170	ACUTE DELTA-(SUPER) INFECTION OF HEPATITIS B CARRIER
B1710	ACUTE HEPATITIS C WITHOUT HEPATIC COMA
B1711	ACUTE HEPATITIS C WITH HEPATIC COMA
B172	ACUTE HEPATITIS E
B178	OTHER SPECIFIED ACUTE VIRAL HEPATITIS
B179	ACUTE VIRAL HEPATITIS, UNSPECIFIED
B180	CHRONIC VIRAL HEPATITIS B WITH DELTA-AGENT
B181	CHRONIC VIRAL HEPATITIS B WITHOUT DELTA-AGENT
B182	CHRONIC VIRAL HEPATITIS C
B188	OTHER CHRONIC VIRAL HEPATITIS
B189	CHRONIC VIRAL HEPATITIS, UNSPECIFIED
B190	UNSPECIFIED VIRAL HEPATITIS WITH HEPATIC COMA
B1910	UNSPECIFIED VIRAL HEPATITIS B WITHOUT HEPATIC COMA
B1911	UNSPECIFIED VIRAL HEPATITIS B WITH HEPATIC COMA
B1920	UNSPECIFIED VIRAL HEPATITIS C WITHOUT HEPATIC COMA
B1921	UNSPECIFIED VIRAL HEPATITIS C WITH HEPATIC COMA
B199	UNSPECIFIED VIRAL HEPATITIS WITHOUT HEPATIC COMA
K700	ALCOHOLIC FATTY LIVER
K7010	ALCOHOLIC HEPATITIS WITHOUT ASCITES
K7011	ALCOHOLIC HEPATITIS WITH ASCITES
K702	ALCOHOLIC FIBROSIS AND SCLEROSIS OF LIVER
K7030	ALCOHOLIC CIRRHOSIS OF LIVER WITHOUT ASCITES
K7031	ALCOHOLIC CIRRHOSIS OF LIVER WITH ASCITES
K7040	ALCOHOLIC HEPATIC FAILURE WITHOUT COMA
K7041	ALCOHOLIC HEPATIC FAILURE WITH COMA
K709	ALCOHOLIC LIVER DISEASE, UNSPECIFIED
K710	TOXIC LIVER DISEASE WITH CHOLESTASIS
K7110	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITHOUT COMA
K7111	TOXIC LIVER DISEASE WITH HEPATIC NECROSIS WITH COMA
K712	TOXIC LIVER DISEASE WITH ACUTE HEPATITIS

Step 4 (diagnosis of PML or hepatic impairment)	
Required quantity: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
K713	TOXIC LIVER DISEASE WITH CHRONIC PERSISTENT HEPATITIS
K714	TOXIC LIVER DISEASE WITH CHRONIC LOBULAR HEPATITIS
K7150	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITHOUT ASCITES
K7151	TOXIC LIVER DISEASE WITH CHRONIC ACTIVE HEPATITIS WITH ASCITES
K716	TOXIC LIVER DISEASE WITH HEPATITIS, NOT ELSEWHERE CLASSIFIED
K717	TOXIC LIVER DISEASE WITH FIBROSIS AND CIRRHOSIS OF LIVER
K718	TOXIC LIVER DISEASE WITH OTHER DISORDERS OF LIVER
K719	TOXIC LIVER DISEASE, UNSPECIFIED
K7200	ACUTE AND SUBACUTE HEPATIC FAILURE WITHOUT COMA
K7201	ACUTE AND SUBACUTE HEPATIC FAILURE WITH COMA
K7210	CHRONIC HEPATIC FAILURE WITHOUT COMA
K7211	CHRONIC HEPATIC FAILURE WITH COMA
K7290	HEPATIC FAILURE, UNSPECIFIED WITHOUT COMA
K7291	HEPATIC FAILURE, UNSPECIFIED WITH COMA
K730	CHRONIC PERSISTENT HEPATITIS, NOT ELSEWHERE CLASSIFIED
K731	CHRONIC LOBULAR HEPATITIS, NOT ELSEWHERE CLASSIFIED
K732	CHRONIC ACTIVE HEPATITIS, NOT ELSEWHERE CLASSIFIED
K738	OTHER CHRONIC HEPATITIS, NOT ELSEWHERE CLASSIFIED
K739	CHRONIC HEPATITIS, UNSPECIFIED
K740	HEPATIC FIBROSIS
K741	HEPATIC SCLEROSIS
K742	HEPATIC FIBROSIS WITH HEPATIC SCLEROSIS
K743	PRIMARY BILIARY CIRRHOSIS
K744	SECONDARY BILIARY CIRRHOSIS
K745	BILIARY CIRRHOSIS, UNSPECIFIED
K7460	UNSPECIFIED CIRRHOSIS OF LIVER
K7469	OTHER CIRRHOSIS OF LIVER
K750	ABSCESS OF LIVER
K751	PHLEBITIS OF PORTAL VEIN
K752	NONSPECIFIC REACTIVE HEPATITIS
K753	GRANULOMATOUS HEPATITIS, NOT ELSEWHERE CLASSIFIED
K754	AUTOIMMUNE HEPATITIS
K7581	NONALCOHOLIC STEATOHEPATITIS (NASH)
K7589	OTHER SPECIFIED INFLAMMATORY LIVER DISEASES
K759	INFLAMMATORY LIVER DISEASE, UNSPECIFIED

Step 4 (diagnosis of PML or hepatic impairment)	
Required quantity: 1	
Look back timeframe: 180 days	
ICD-10 Code	Description
K761	CHRONIC PASSIVE CONGESTION OF LIVER
K763	INFARCTION OF LIVER
K7689	OTHER SPECIFIED DISEASES OF LIVER
K769	LIVER DISEASE, UNSPECIFIED
K77	LIVER DISORDERS IN DISEASES CLASSIFIED ELSEWHERE



Cytokine and CAM Antagonists

Clinical Criteria References

1. Clinical Pharmacology [online database]. Tampa, FL: Elsevier / Gold Standard, Inc. 2023. Available at <http://www.clinicalpharmacology.com>. Accessed on December 5, 2023.
2. Entyvio Prescribing Information. Lexington, MA. Takeda Pharmaceuticals USA, Inc. September 2023.

Publication History

The Publication History records the publication iterations and revisions to this document. Notes for the *most current revision* are also provided in the **Revision Notes** on the first page of this document.

Publication Date	Notes
01/26/2024	Initial publication and presentation to the DUR Board