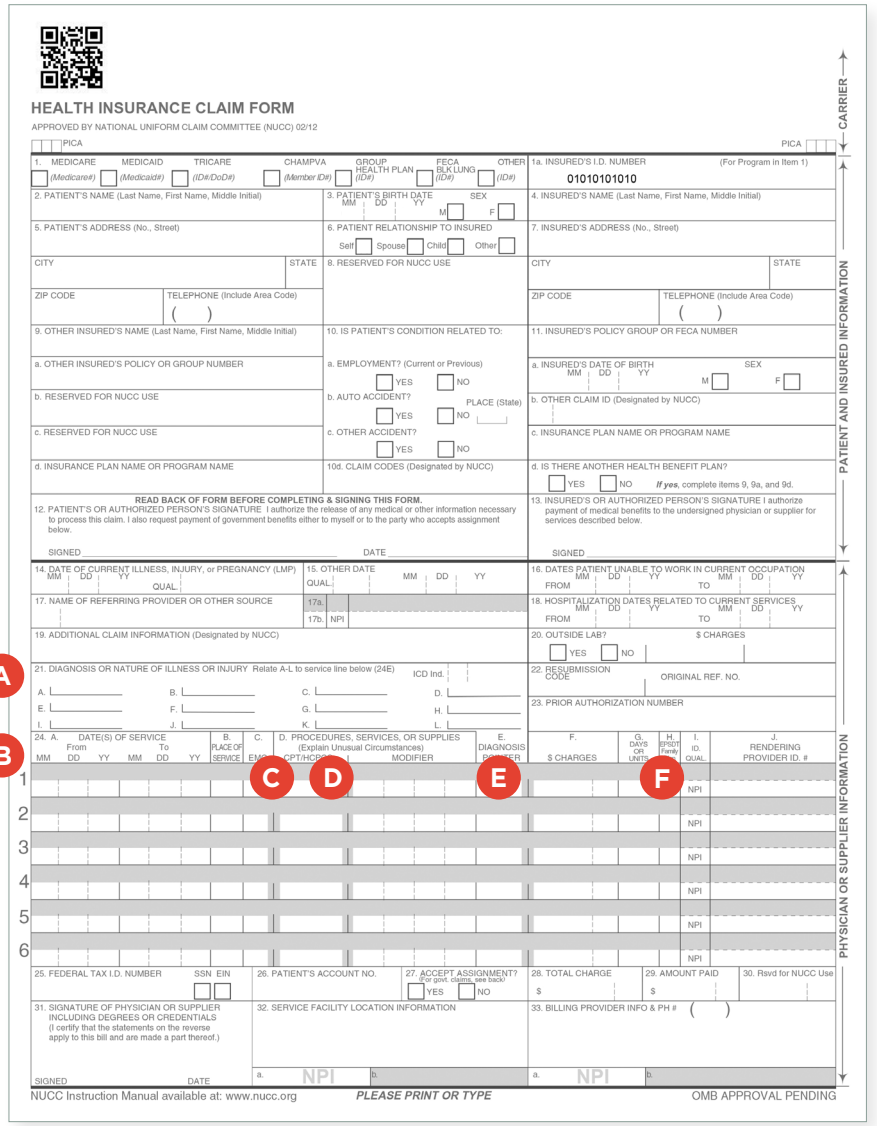
5 PHYSICIAN OFFICE SAMPLE CMS-1500 CLAIM FORM[1]

The CMS-1500 claim form is the standard claim form to bill many government and private insurers. The sample here is intended to assist you with completing the form for billing Entyvio and associated services.

- **A Diagnosis Code | Box 21** Document appropriate ICD diagnosis code(s) corresponding to patient's diagnosis. Line 1—primary diagnosis code
- **B Product information | Box 24A** Supplemental information may be entered in the shaded section. Providers must verify information requirements with the payer
- **C Product Code | Box 24D** Document use of product with appropriate code (eg, J-code) depending on the plan
- **D Procedure Code | Box 24D** Use the CPT code representing procedure performed, as required by payer
- **E Diagnosis Pointer | Box 24E** Specify diagnosis, from Box 21, related to each CPT/HCPCS code listed in Box 24D. This may be in a letter or number depending on the payer
- **F Service Units | Box 24G** Report number of units (300 units = one 300-mg vial)

Click here for a CMS-1500 CLAIM FORM you can fill out.

For questions, please call **1-855-ENTYVIO** (1-855-368-9846), Monday to Friday, from 8 AM to 8 PM EST (except holidays)



Sample patient information is shown for illustrative purposes only.

This billing guide does not represent a promise or guarantee of coverage and payment for any individual patient or treatment. Correct coding is the responsibility of the provider submitting a claim for the item or service. Please check with the payer to verify codes and any special billing requirements or call **1-855-ENTYVIO** (1-855-368-9846), Monday through Friday, from 8 AM to 8 PM EST (except holidays), for guidance on completing the form.

Please see Indications and Important Safety Information on next page.

INDICATIONS: ENTYVIO (vedolizumab)

Adult Ulcerative Colitis (UC)

Adult patients with moderately to severely active UC who have had an inadequate response with, lost response to, or were intolerant to a tumor necrosis factor (TNF) blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- inducing and maintaining clinical response
- inducing and maintaining clinical remission
- improving endoscopic appearance of the mucosa
- achieving corticosteroid-free remission

Adult Crohn's Disease (CD)

Adult patients with moderately to severely active CD who have had an inadequate response with, lost response to, or were intolerant to a TNF blocker or immunomodulator; or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids:

- achieving clinical response
- achieving clinical remission
- achieving corticosteroid-free remission

IMPORTANT SAFETY INFORMATION

- ENTYVIO (vedolizumab) for injection is contraindicated in patients who have had a known serious or severe hypersensitivity reaction to ENTYVIO or any of its excipients.
- Infusion-related reactions and hypersensitivity reactions including anaphylaxis have occurred. Allergic reactions including dyspnea, bronchospasm, urticaria, flushing, rash, and increased blood pressure and heart rate have also been observed. If anaphylaxis or other serious allergic reactions occur, discontinue administration of ENTYVIO immediately and initiate appropriate treatment.

Reference: 1. Centers for Medicare and Medicaid Services. CMS forms list. http://cms.gov/medicare/cms-forms/cms-forms/cms-forms-list.html. Accessed July 22, 2015.

IMPORTANT SAFETY INFORMATION (continued)

- Patients treated with ENTYVIO are at increased risk for developing infections. Serious infections have been reported in patients treated with ENTYVIO, including anal abscess, sepsis (some fatal), tuberculosis, salmonella sepsis, Listeria meningitis, giardiasis, and cytomegaloviral colitis. ENTYVIO is not recommended in patients with active, severe infections until the infections are controlled. Consider withholding ENTYVIO in patients who develop a severe infection while on treatment with ENTYVIO. Exercise caution in patients with a history of recurring severe infections. Consider screening for tuberculosis (TB) according to the local practice.
- Although no cases of PML have been observed in ENTYVIO clinical trials, JC virus infection resulting in progressive multifocal leukoencephalopathy (PML) and death has occurred in patients treated with another integrin receptor antagonist. A risk of PML cannot be ruled out. Monitor patients for any new or worsening neurological signs or symptoms. Typical signs and symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes. If PML is suspected, withhold dosing with ENTYVIO and refer to a neurologist; if confirmed, discontinue ENTYVIO dosing permanently.
- There have been reports of elevations of transaminase and/or bilirubin in patients receiving ENTYVIO. ENTYVIO should be discontinued in patients with jaundice or other evidence of significant liver injury.
- Prior to initiating treatment with ENTYVIO, all patients should be brought up to date with all immunizations according to current immunization guidelines. Patients receiving ENTYVIO may receive non-live vaccines and may receive live vaccines if the benefits outweigh the risks.
- Most common adverse reactions (incidence ≥3% and ≥1% higher than placebo): nasopharyngitis, headache, arthralgia, nausea, pyrexia, upper respiratory tract infection, fatigue, cough, bronchitis, influenza, back pain, rash, pruritus, sinusitis, oropharyngeal pain, and pain in extremities.

Please click here to read the full Prescribing Information, including Medication Guide.

April 2016 USD/VED/16/0050