AVSOLA® Billing and Coding Guide

AVSOLA® is a biosimilar to Remicade® backed by Amgen expertise[1]

FOR PHYSICIAN OFFICES USING THE CMS 1500

FOR HOSPITALS/INSTITUTIONS USING THE CMS 1450

AMGEN Support+ | Call Amgen® SupportPlus for assistance with specific payer requirements: **(866)-264-2778**, Monday - Friday, 9 am - 8 pm ET

For 340B Modifier: Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers "JG" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. Additional provider types will be required to use these modifiers in 2024.[2]

INDICATIONS

AVSOLA® is indicated for:

- **Crohn's Disease:** Reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy. AVSOLA® is indicated for reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing Crohn's disease.
- **Pediatric Crohn's Disease:** Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age or older with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy.
- **Ulcerative Colitis:** Reducing signs and symptoms, inducing and maintaining clinical remission and mucosal healing, and eliminating corticosteroid use in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- **Pediatric Ulcerative Colitis:** Reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients 6 years of age and older with moderately to severely active ulcerative colitis who have had an inadequate response to conventional therapy.
- **Rheumatoid Arthritis in combination with methotrexate:** Reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.
- **Ankylosing Spondylitis:** Reducing signs and symptoms in adult patients with active ankylosing spondylitis.
- **Psoriatic Arthritis:** Reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function in adult patients with psoriatic arthritis.
- **Plaque Psoriasis:** The treatment of adult patients with chronic severe (i.e., extensive and/or disabling) plaque psoriasis who are candidates for systemic therapy and when other systemic therapies are medically less appropriate. AVSOLA® should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

Please see full Important Safety Information on pages 6-7.

BILLING AND CODING

NATIONAL DRUG CODE (NDC)[1]		
55513-670-01	10-digit NDC	Single-dose vial containing 100 mg of AVSOLA® for final reconstitution volume of 10 mL
55513-0670-01	11-digit NDC	

HCPCS[2,3]
Q5121 Injection, infliximab-axxq, biosimilar, (AVSOLA®), 10 mg

JW/JZ Modifier in Box 24D†	Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (Drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.†

Healthcare providers should consult the payer or Medicare contractor to determine which CPT® code(s) is most appropriate for administration of AVSOLA®. The codes listed below are not an exhaustive list of drug administration services. Please refer to the CPT® manual for a complete list of drug administration codes.

†Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

CPT®[5]	
96413	Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug
96415	Chemotherapy administration, intravenous infusion technique; each additional hour. (List separately in addition to code for primary procedure)
96365	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); initial, up to 1 hour
96366	Intravenous infusion, for therapy, prophylaxis, or diagnosis (specify substance or drug); each additional hour. (List separately in addition to code for primary procedure)

REVENUE CODES[6] (hospital setting only)			
0636	Drugs requiring detailed coding	**0250**	General pharmacy

AVSOLA® BILLING UNITS		
Number of 100 mg vials of AVSOLA®	**Total milligrams (mg)**	**Number of Q5121 billing units (10 mg infliximab-axxq biosimilar per unit)**
1	100	10 units
2	200	20 units
3	300	30 units
4	400	40 units
5	500	50 units

SELECT IMPORTANT SAFETY INFORMATION

Serious and sometimes fatal side effects have been reported with infliximab products. Infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens (eg, TB, histoplasmosis) have been reported. Lymphoma, including cases of fatal hepatosplenic T-cell lymphoma (HSTCL), and other malignancies have been reported, including in children and young adult patients. Due to the risk of HSTCL, mostly reported in Crohn's disease and ulcerative colitis, assess the risk/benefit, especially if the patient is male and is receiving azathioprine or 6-mercaptopurine treatment. AVSOLA® is contraindicated at doses >5 mg/kg in patients with moderate or severe heart failure and in patients with severe hypersensitivity reactions to infliximab. Other serious side effects reported include melanoma, Merkel cell carcinoma, invasive cervical cancer, hepatitis B reactivation, hepatotoxicity, hematological events, hypersensitivity, cardiovascular and cerebrovascular reactions during and after infusion, neurological events, and lupus-like syndrome.
Please see related and other Important Safety Information on pages 6-7.

BILLING AND CODING (cont'd)

The ICD-10-CM codes provided below are not an exhaustive list, and payers may require a higher level of specificity. Please refer to the ICD-10-CM manual for a complete list of diagnosis codes, including those with complications.

COMMON ICD-10-CM CODES[7]	
	MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE
K50.00	Crohn's disease of small intestine without complications
K50.10	Crohn's disease of large intestine without complications
K50.80	Crohn's disease of both small and large intestine without complications
K50.90	Crohn's disease, unspecified, without complications
	FISTULA (use in addition to codes for Crohn's disease)
K60.3	Anal fistula
K60.4	Rectal fistula
	MODERATELY TO SEVERELY ACTIVE ULCERATIVE COLITIS
K51.00	Ulcerative (chronic) pancolitis without complications
K51.20	Ulcerative (chronic) proctitis without complications
K51.30	Ulcerative (chronic) rectosigmoiditis without complications
K51.50	Left-sided colitis without complications
K51.80	Other ulcerative colitis without complications
K51.90	Ulcerative colitis, unspecified, without complications
	MODERATELY TO SEVERELY ACTIVE RHEUMATOID ARTHRITIS
M05.60	Rheumatoid arthritis of unspecified site with involvement of other organs and systems
M05.70	Rheumatoid arthritis with rheumatoid factor of unspecified site without organ or systems involvement
M06.00	Rheumatoid arthritis without rheumatoid factor, unspecified site
	ACTIVE ANKYLOSING SPONDYLITIS
M45.9	Ankylosing spondylitis of unspecified sites in spine
	ACTIVE PSORIATIC ARTHRITIS
L40.50	Arthropathic psoriasis, unspecified
	CHRONIC SEVERE PLAQUE PSORIASIS
L40.0	Psoriasis vulgaris

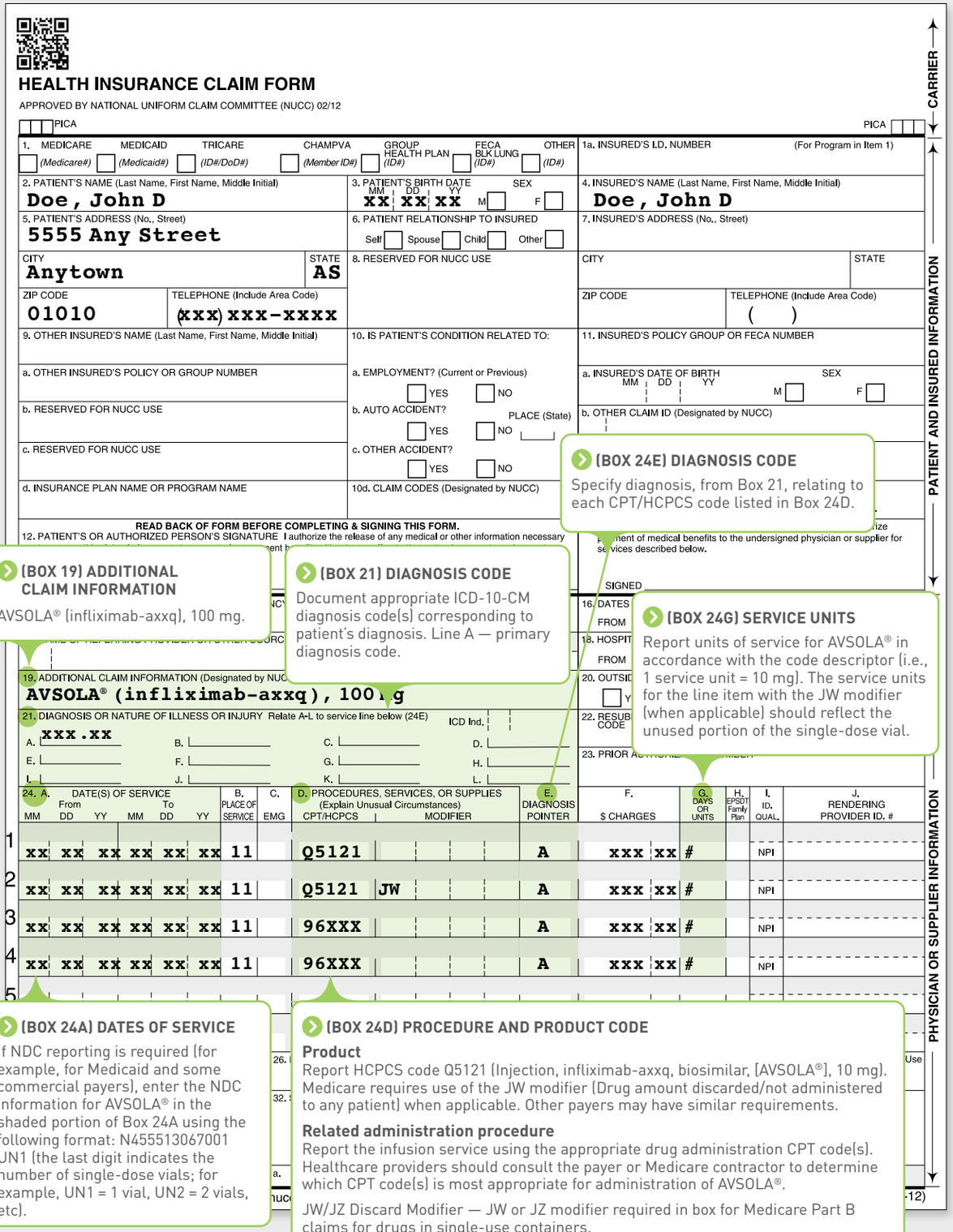
The information provided in this document is of a general nature and for informational purposes only and is not intended to be a comprehensive list nor instructive. Coding and coverage policies change periodically and often without warning. The responsibility to determine coverage and reimbursement parameters, and appropriate coding for a particular patient and/or procedure, is always the responsibility of the provider or physician. The information provided in this document should in no way be considered a guarantee of coverage or reimbursement for any product or service.

CPT=Current Procedural Terminology; HCPCS=Healthcare Common Procedure Coding System; ICD-10-CM=International Classification of Diseases, Tenth Revision, Clinical Modification.

AVSOLA® (infliximab-axxq) For Injection 100mg/vial

The CMS 1500 for Physician Office

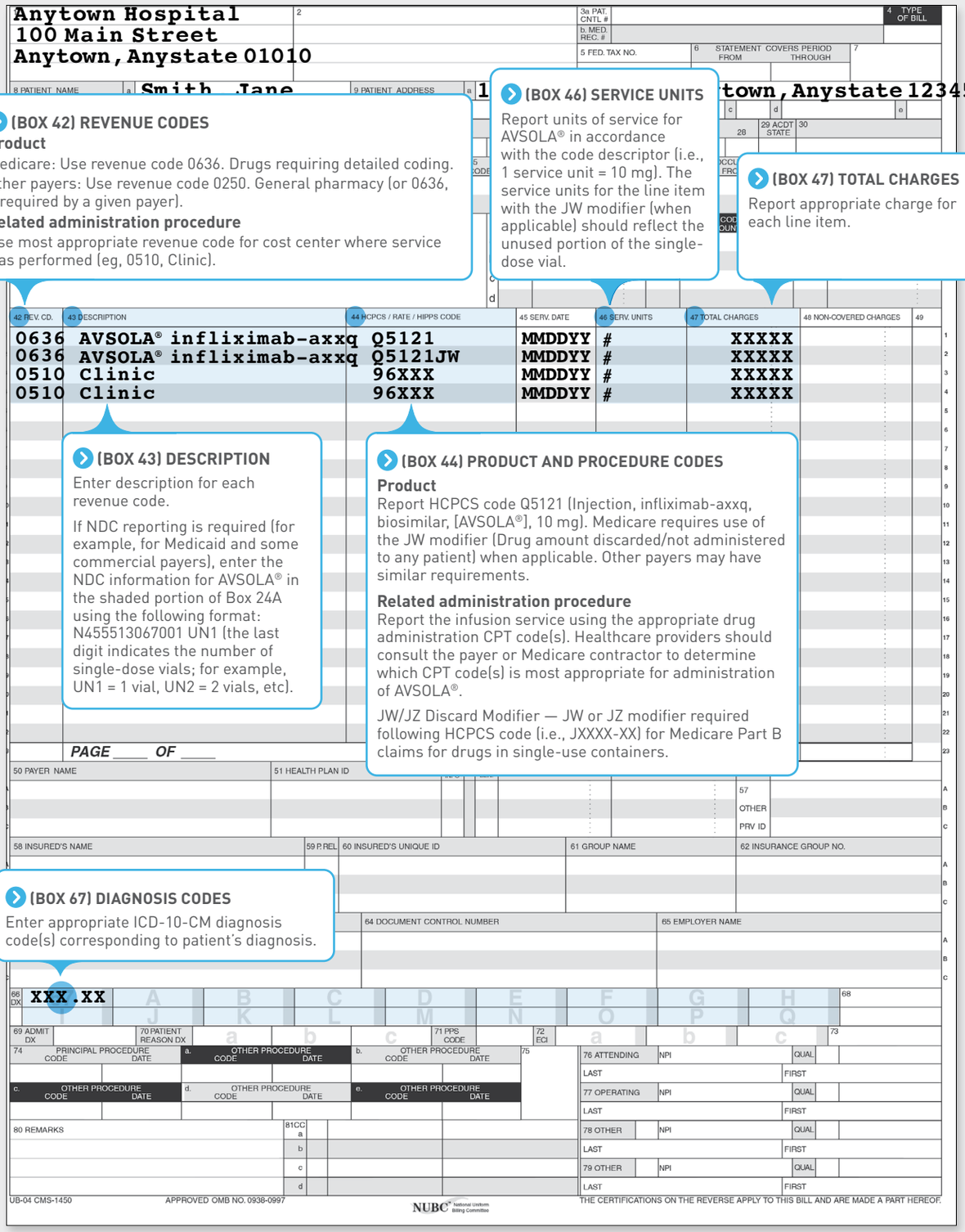
Sample CMS 1500 Form — Physician Office Administration



This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration



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IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS: Patients treated with infliximab products are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Discontinue AVSOLA® if a patient develops a serious infection or sepsis.

Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients frequently presented with disseminated or extrapulmonary disease. Patients should be tested for latent TB before AVSOLA® use and during therapy. Treatment for latent infection should be initiated prior to AVSOLA® use.**
- **Invasive fungal infections including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, pneumocystosis and cryptococcosis. Patients may present with disseminated, rather than localized, disease. Empiric anti-fungal therapy should be considered in patients at risk for invasive fungal infections who develop severe systemic illness.**
- **Bacterial, viral, and other infections due to opportunistic pathogens, including Legionella, Listeria, and Salmonella.**

The risks and benefits of treatment with AVSOLA® should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection. Patients should be closely monitored for the development of signs and symptoms of infection during and after treatment with AVSOLA®, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy, who are on treatment for latent TB, or who were previously treated for TB infection.

Risk of infection may be higher in patients greater than 65 years of age, pediatric patients, patients with co-morbid conditions and/or patients taking concomitant immunosuppressant therapy. In clinical trials, other serious infections observed in patients treated with infliximab products included pneumonia, cellulitis, abscess, and skin ulceration.

MALIGNANCIES

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products. Approximately half of these cases were lymphomas, including Hodgkin's and non-Hodgkin's lymphoma. The other cases represented a variety of malignancies, including rare malignancies that are usually associated with immunosuppression and malignancies that are not usually observed in children and adolescents. The malignancies occurred after a median of 30 months after the first dose of therapy. Most of the patients were receiving concomitant immunosuppressants.

Postmarketing cases of hepatosplenic T-cell lymphoma, a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including infliximab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported cases have occurred in patients with Crohn's disease or ulcerative colitis and most were in adolescent and young adult males. Almost all patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. Carefully assess the risks and benefits of treatment with AVSOLA®, especially in these patient types.

In clinical trials of all TNF inhibitors, more cases of lymphoma were observed compared with controls and the expected rate in the general population. However, patients with Crohn's disease, rheumatoid arthritis, or plaque psoriasis may be at higher risk for developing lymphoma. In clinical trials of some TNF inhibitors, including infliximab products, more cases of other malignancies were observed compared with controls. The rate of these malignancies among patients treated with infliximab products was similar to that expected in the general population, whereas the rate in control patients was lower than expected. Cases of acute and chronic leukemia have been reported with postmarketing TNF-blocker use. As the potential role of TNF inhibitors in the development of malignancies is not known, caution should be exercised when considering treatment of patients with a current or a past history of malignancy or other risk factors such as chronic obstructive pulmonary disease (COPD).

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocker therapy, including infliximab products. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

A population-based retrospective cohort study found a 2- to 3-fold increase in the incidence of invasive cervical cancer in women with rheumatoid arthritis treated with infliximab compared to biologics-naïve patients or the general population, particularly those over 60 years of age. A causal relationship between infliximab products and cervical cancer cannot be excluded. Periodic screening should continue in women treated with AVSOLA®.

CONTRAINDICATIONS

The use of AVSOLA® at doses >5 mg/kg is contraindicated in patients with moderate or severe heart failure. AVSOLA® is contraindicated in patients with a previous severe hypersensitivity reaction to infliximab or any of the inactive ingredients of AVSOLA® or any murine proteins (severe hypersensitivity reactions have included anaphylaxis, hypotension, and serum sickness).

HEPATITIS B REACTIVATION

TNF inhibitors, including infliximab products, have been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases were fatal. Patients should be tested for HBV infection before initiating AVSOLA®. For patients who test positive, consult a physician with expertise in the treatment of hepatitis B. Exercise caution when prescribing AVSOLA® for patients identified as carriers of HBV and monitor closely for active HBV infection during and following termination of therapy with AVSOLA®. Discontinue AVSOLA® in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution

when considering resumption of TNF-blocker therapy and monitor patients closely.

HEPATOTOXICITY

Severe hepatic reactions, including acute liver failure, jaundice, hepatitis, and cholestasis have been reported in patients receiving infliximab products postmarketing. Some cases were fatal or required liver transplant. Aminotransferase elevations were not noted prior to discovery of liver injury in many cases. Patients with symptoms or signs of liver dysfunction should be evaluated for evidence of liver injury. If jaundice and/or marked liver enzyme elevations (eg, ≥ 5 times the upper limit of normal) develop, AVSOLA® should be discontinued, and a thorough investigation of the abnormality should be undertaken.

HEART FAILURE

In a randomized, placebo-controlled study in patients with moderate or severe heart failure (NYHA Functional Class III/IV), higher mortality rates and a higher risk of hospitalization were observed at Week 28 at a dose of 10 mg/kg and higher rates of cardiovascular events were observed at both 5 mg/kg and 10 mg/kg. There have been postmarketing reports of new onset and worsening heart failure, with and without identifiable precipitating factors. Patients with moderate or severe heart failure taking infliximab (≤5 mg/kg) or patients with mild heart failure should be closely monitored and treatment should be discontinued if new or worsening symptoms appear.

HEMATOLOGIC REACTIONS

Cases of leukopenia, neutropenia, thrombocytopenia, and pancytopenia (some fatal) have been reported in patients receiving infliximab products. The causal relationship to infliximab product therapy remains unclear. Exercise caution in patients who have ongoing or a history of significant hematologic abnormalities. Advise patients to seek immediate medical attention if they develop signs and symptoms of blood dyscrasias or infection. Consider discontinuation of AVSOLA® in patients who develop significant hematologic abnormalities.

HYPERSENSITIVITY

Infliximab products have been associated with hypersensitivity reactions that differ in their time of onset. Anaphylaxis, urticaria, dyspnea, and hypotension have occurred in association with infusions of infliximab products. Medications for the treatment of hypersensitivity reactions should be available.

CARDIOVASCULAR AND CEREBROVASCULAR REACTIONS DURING AND AFTER INFUSION

Serious cerebrovascular accidents, myocardial ischemia/infarction (some fatal), hypotension, hypertension, and arrhythmias have been reported during and within 24 hours of initiation of infliximab product infusion. Cases of transient visual loss have been reported during or within 2 hours of infusion of infliximab. Monitor patients during infusion and if a serious reaction occurs, discontinue infusion. Manage reactions according to signs and symptoms.

NEUROLOGIC REACTIONS

Agents that inhibit TNF have been associated with CNS manifestation of systemic vasculitis, seizure, and new onset or exacerbation of CNS demyelinating disorders, including multiple sclerosis and optic neuritis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Exercise caution when considering AVSOLA® in patients with these disorders and consider discontinuation if these disorders develop.

CONCURRENT ADMINISTRATION WITH OTHER BIOLOGICS

Concomitant use of AVSOLA® with anakinra, abatacept, tocilizumab, or other biologics used to treat the same conditions as AVSOLA® is not recommended because of the possibility of an increased risk of infection. Care should be taken when switching from one biologic to another, since overlapping biological activity may further increase the risk of infection.

AUTOIMMUNITY

Treatment with infliximab products may result in the formation of autoantibodies and in the development of a lupus-like syndrome. Discontinue treatment with AVSOLA® if symptoms of a lupus-like syndrome develop.

VACCINATIONS AND USE OF LIVE VACCINES/ THERAPEUTIC INFECTIOUS AGENTS

Bring patients up to date with all vaccinations prior to initiating AVSOLA®. Live vaccines or therapeutic infectious agents should not be given with AVSOLA® due to the possibility of clinical infections, including disseminated infections.

At least a 6-month waiting period following birth is recommended before the administration of any live vaccine to infants exposed *in utero* to infliximab products.

ADVERSE REACTIONS

In clinical trials with infliximab products, the most common adverse reactions occurring in >10% of patients included infections (eg, upper respiratory, sinusitis, and pharyngitis), infusion-related reactions, headache, and abdominal pain.

Please click here for full Prescribing Information.

AVSOLA®
(infliximab-axxq)
For Injection 100mg/vial

BUSINESS CARD SLEEVE

Your Amgen representative can connect you with an Access Specialist or call **(866)-772-6436**, Monday - Friday, 8:00am - 8:00pm ET

References: 1. AVSOLA® (infliximab-axxq) prescribing information, Amgen. **2.** CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers, December 20, 2022, available at https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf. Accessed May 17, 2023. **3.** CMS, Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy FAQs (January 2023), available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. Accessed May 17, 2023. **4.** Centers for Medicare & Medicaid Services. Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Decisions. https://www.cms.gov/files/document/2020-hcpcs-application-summary-quarter-1-2020-drugs-and-biologicals.pdf. Accessed May 19, 2023. **5.** American Medical Association. *CPT® 2020 Professional Edition*. American Medical Association; 2019. **6.** Noridian Healthcare Solutions. Revenue Codes. https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes. Accessed May 19, 2023. **7.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. https://www.cms.gov/Medicare/Coding/ICD10/Downloads/2020-ICD-10-CM-Code-Tables.zip. Accessed May 19, 2023.

Reimbursement Disclaimer

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Please see Important Safety Information on pages 6-7 and click here for full Prescribing Information.

Please visit **AVSOLA.com** for additional information and resources.

Call **1-800-77-AMGEN (1-800-772-6436)** if you have questions about ordering and accessing AVSOLA®.

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