



Fax with copies of insurance card(s), front and back, to Amgen Assist®: 1-833-4-AVSOLA (1-833-428-7652)

# Benefits Verification Form

## Patient Information

\*Patient Name: \_\_\_\_\_  
 Attach patient demographic sheet **OR** Complete information below:  
 \*Street Address: \_\_\_\_\_  
 \*City: \_\_\_\_\_ \*State: \_\_\_\_\_ \*Zip: \_\_\_\_\_  
 \*Phone: \_\_\_\_\_  
 M  F \*Date of Birth: \_\_\_\_\_  
 Email: \_\_\_\_\_

## Prescribing Physician Information

\*Physician Name: \_\_\_\_\_  
 \*NPI #: \_\_\_\_\_ \*Tax ID #: \_\_\_\_\_  
 Specialty: \_\_\_\_\_  
 \*Enter Site ID: \_\_\_\_\_ **OR** Complete information below.  
 \*Site Name: \_\_\_\_\_  
 \*Street Address: \_\_\_\_\_  
 \*City: \_\_\_\_\_ \*State: \_\_\_\_\_ \*Zip: \_\_\_\_\_  
 \*Phone: \_\_\_\_\_  
 \*Fax: \_\_\_\_\_  
 Office Contact: \_\_\_\_\_  
 Physician Email: \_\_\_\_\_  
 \*Site Type:  MD Office  Hospital Outpatient

## Therapy With AVSOLA™

Dosage/Frequency:  
**For Crohn's Disease, Pediatric Crohn's Disease, Ulcerative Colitis, Psoriatic Arthritis, Plaque Psoriasis:**  
 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks  
 Other: Dosage \_\_\_\_\_ Frequency \_\_\_\_\_  
**For Ankylosing Spondylitis:**  
 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks  
**For Rheumatoid Arthritis (in conjunction with MTX):**  
 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks  
 Other: Dosage \_\_\_\_\_ Frequency \_\_\_\_\_  
 Patient weight \_\_\_\_\_ kg # of vials to be used \_\_\_\_\_  
 Anticipated # of infusions \_\_\_\_\_

## Fulfillment Method (Select only ONE)

**(Defaults to Medical Benefit)**  
 Medical Benefit (Physician Purchase)  
 Referral to treating site  
 \*Site ID: \_\_\_\_\_ **OR** Complete information below.  
 \*Site Name: \_\_\_\_\_  
 \*Street Address: \_\_\_\_\_  
 \*City: \_\_\_\_\_ \*State: \_\_\_\_\_ \*Zip: \_\_\_\_\_  
 \*Phone: \_\_\_\_\_  
 \*Fax: \_\_\_\_\_  
 Office Contact: \_\_\_\_\_  
 \*Site Type:  MD Office  Hospital Outpatient

## Primary Insurance Information

Attach a copy of insurance card, front **AND** back **OR** provide:  
 \*Insurance Name: \_\_\_\_\_  
 \*Insurance Phone: \_\_\_\_\_  
 Subscriber Name: \_\_\_\_\_  
 Subscriber Date of Birth: \_\_\_\_\_  
 Subscriber Relationship to Patient: \_\_\_\_\_  
 Group #: \_\_\_\_\_  
 \*Policy #: \_\_\_\_\_

## Secondary Insurance Information (If Applicable)

Attach a copy of insurance card, front **AND** back **OR** provide:  
 \*Insurance Name: \_\_\_\_\_  
 \*Is this a Medigap policy?  Yes  No  Not Known  
 If yes, please indicate plan letter: \_\_\_\_\_  
 \*Insurance Phone: \_\_\_\_\_  
 Subscriber Name: \_\_\_\_\_  
 Subscriber Date of Birth: \_\_\_\_\_  
 Subscriber Relationship to Patient: \_\_\_\_\_  
 Group #: \_\_\_\_\_  
 \*Policy #: \_\_\_\_\_

\*Asterisk fields are required for processing. If you have any questions, please contact Amgen Assist® at 1-866-AMG-ASST (1-866-264-2778). Please see AVSOLA™ Indications on page 2 and Important Safety Information on pages 3 and 4.

**By completing and faxing this form, you represent that your patient is aware of the disclosure of their personal health information to Amgen and its agents for Amgen's patient support services, including reimbursement and verification services and the services provided by field reimbursement professionals in your office, as part of the patient's treatment with this product and that you have obtained appropriate patient authorizations as needed.**

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## Primary Diagnosis (select one)

- Crohn's Disease
  - K50.90 (Crohn's disease, unspecified, without complications)
  - Other \_\_\_\_\_
- Ulcerative Colitis
  - K51.80 (Other ulcerative colitis without complications)
  - Other \_\_\_\_\_
- Rheumatoid Arthritis
  - M05.9 (RA with rheumatoid factor, unspecified)
  - Other \_\_\_\_\_
- Ankylosing Spondylitis
  - M45.9 (Ankylosing Spondylitis of unspecified sites in spine)
  - Other \_\_\_\_\_
- Psoriatic Arthritis
  - L40.5 (Arthropathic psoriasis, unspecified)
  - Other \_\_\_\_\_
- Plaque Psoriasis
  - L40.0 (Psoriasis)
  - Other \_\_\_\_\_

## Clinical Information

Please list all current treatments and prior treatments associated with the indications provided above.

List Current/Prior Treatments	Treatment Length (mm/yyyy)		Current Treatment
	From	To	
1. Methotrexate <input type="checkbox"/> Y <input type="checkbox"/> N	_____	_____	<input type="checkbox"/>
2. _____	_____	_____	<input type="checkbox"/>
3. _____	_____	_____	<input type="checkbox"/>
4. _____	_____	_____	<input type="checkbox"/>
5. _____	_____	_____	<input type="checkbox"/>

- TB/PPD Test Date \_\_\_\_\_  Pos  Neg
- Hep B Test (optional) Date \_\_\_\_\_  Pos  Neg

## Indications and Usage

AVSOLA™ is a tumor necrosis factor (TNF) blocker indicated for:

### Crohn's Disease:

- reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active disease who have had an inadequate response to conventional therapy.
- reducing the number of draining enterocutaneous and rectovaginal fistulas and maintaining fistula closure in adult patients with fistulizing disease.

*Pediatric Crohn's Disease:* reducing signs and symptoms and inducing and maintaining clinical remission in pediatric patients with moderately to severely active 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 disease 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 with moderately to severely active disease 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 patients with moderately to severely active disease.

*Ankylosing Spondylitis:* reducing signs and symptoms in patients with active disease.

*Psoriatic Arthritis:* reducing signs and symptoms of active arthritis, inhibiting the progression of structural damage, and improving physical function.

*Plaque Psoriasis:* 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.

Please see AVSOLA™ Indications on page 2 and Important Safety Information on pages 3 and 4.

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## Important Safety Information for AVSOLA™ (infliximab-axxq) 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 biologic-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

AVSOLA™ is contraindicated in patients with moderate to severe (NYHA Class III/IV) congestive heart failure (CHF) at doses greater than 5 mg/kg. Higher mortality rates at the 10 mg/kg dose and higher rates of cardiovascular events at the 5 mg/kg dose have been observed in these patients. AVSOLA™ should be used with caution and only after consideration of other treatment options. Patients should be monitored closely. Discontinue AVSOLA™ if new or worsening CHF symptoms appear. AVSOLA™ should not be (re)administered to patients who have experienced a severe hypersensitivity reaction or to patients with hypersensitivity to murine proteins or other components of the product.

### 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 (e.g.,  $\geq 5$  times the upper limit of normal) develop, AVSOLA™ should be discontinued, and a thorough investigation of the abnormality should be undertaken.

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## Important Safety Information for AVSOLA™ (continued)

### 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.

### 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.

### Adverse Reactions

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

### Use With Other Drugs

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.

### Live Vaccines/Therapeutic Infectious Agents

Live vaccines or therapeutic infectious agents should not be given with AVSOLA™ due to the possibility of clinical infections, including disseminated infections.

Bring pediatric patients up to date with all vaccinations prior to initiating AVSOLA™. 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.

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