Infliximab Intravenous (Remicade®, Inflectra®, Renflexis®, Avsola™, Infliximab)

When requesting an infliximab intravenous product (Remicade, Inflectra, Renflexis, Avsola, Infliximab), the individual requiring treatment must be diagnosed with one of the following FDA-approved indications or approved off-label compendial uses and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indications

Infliximab intravenous is indicated for the treatment of:

- Crohn's disease
- Ulcerative colitis
- Rheumatoid arthritis
- Psoriatic arthritis
- Plaque psoriasis
- Ankylosing spondylitis

Approved Off-label Compendial Uses

- Behcet's disease
- Graft-versus-host disease
- Hidradenitis suppurativa
- Colitis, indeterminate
- Juvenile idiopathic arthritis
- Pyoderma gangrenosum
- Sarcoidosis
- Scleritis or sterile corneal ulceration
- Still's disease
- Spondyloarthritis, other subtypes
- Uveitis
- Immunotherapy-related toxicities associated with checkpoint inhibitor therapy

Coverage Guidelines

Rheumatoid Arthritis (RA)

The individual must meet all of the following criteria for initial authorization:

- Is 18 years of age or older;
- Had a 3-month trial of at least one biologic agent or at least one conventional synthetic disease-modifying antirheumatic drug (DMARD);
- Infliximab intravenous is prescribed by or in consultation with a rheumatologist.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Clinical Disease Activity Index [CDAI], Patient Activity Scale [PAS]-II, Rapid Assessment of Patient Index Data 3 [RAPID-3], etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints).

Ankylosing Spondylitis (AS)

The individual must meet both of the following criteria for initial authorization:

- Is 18 years of age or older;
- Infliximab intravenous is prescribed by or in consultation with a rheumatologist.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Ankylosing Spondylitis Disease Activity Score [ASDAS], Ankylosing Spondylitis Quality of Life Scale [ASQoL], Bath Ankylosing Spondylitis Disease Activity Index [BASDAI], serum markers [e.g., C-reactive protein, erythrocyte sedimentation rate], etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain or stiffness; improvement in function or activities of daily living).

Psoriatic Arthritis (PsA)

The individual must meet both of the following criteria for initial authorization:

- Is 18 years of age or older;
- Infliximab intravenous is prescribed by or in consultation with a rheumatologist or a dermatologist.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:

- Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Disease Activity Index for Psoriatic Arthritis [DAPSA], Composite Psoriatic Disease Activity Index [CPDAI], Psoriatic Arthritis Disease Activity Score [PsA DAS], Psoriatic Arthritis Impact of Disease [PsAID-12], and/or serum markers); OR
- Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain, morning stiffness, or fatigue; improved function or activities of daily living; decreased soft tissue swelling in joints).

Crohn's Disease (CD)

The individual must meet all of the following criteria for initial authorization:
- Is 6 years of age or older;
- Meets one of the following:
  - Has tried one other systemic agent for Crohn's disease (e.g., certolizumab, adalimumab, vedolizumab, ustekinumab, methotrexate, 6-mercaptopurine); OR
    (Note: A trial of a mesalamine product or a biosimilar of the requested biologic do not count as systemic therapy for Crohn's disease).
  - Has tried or is currently taking corticosteroids; OR
  - Has a contraindication to corticosteroid therapy; OR
  - Has enterocutaneous (perianal or abdominal) or rectovaginal fistulas; OR
  - Had ileocolonic resection.
- Infliximab intravenous is prescribed by or in consultation with a gastroenterologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
  - Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
  - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or blood in stool).

Ulcerative Colitis (UC)

The individual must meet both of the following criteria for initial authorization:
- Is 6 years of age or older;
- Infliximab intravenous is prescribed by or in consultation with a gastroenterologist.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding).

Plaque Psoriasis (PP)

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Meets one of the following:
    - Had a 3-month trial of or intolerance to at least one biologic agent; OR
    - Had a 3-month trial of or intolerance to at least one traditional systemic agent (e.g., methotrexate, cyclosporine, acitretin, psoralen plus ultraviolet A light [PUVA]); OR
    - Has a contraindication to methotrexate therapy;
- Infliximab intravenous is prescribed by or in consultation with a dermatologist.

The individual must meet all of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 3 months *(Note: A patient who has received < 3 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Has experienced a beneficial clinical response from baseline in at least one of the following: estimated body surface area affected, erythema, induration/thickness, and/or scale of areas affected by psoriasis;
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, itching and/or burning).

Behcet's Disease

The individual must meet all of the following criteria for initial authorization:
- Is 6 years of age or older;
- Meets one of the following:
    - Has ophthalmic manifestations of Behcet's disease; OR
    - Had a trial of at least one tumor necrosis factor (TNF) inhibitor (e.g., adalimumab, etanercept); OR
    - Has tried at least one conventional therapy (e.g., systemic corticosteroids, immunosuppressant [e.g., azathioprine, methotrexate, mycophenolate mofetil]);

- Infliximab intravenous is prescribed by or in consultation with one of the following specialists: rheumatologist, dermatologist, ophthalmologist, gastroenterologist, or neurologist.

The individual must meet all of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 3 months *(Note: A patient who has received < 3 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., best-corrected visual acuity if ophthalmic manifestations, serum markers, ulcer depth, number and/or lesion size);
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, improved visual acuity if ophthalmic manifestations).

Graft-versus-Host Disease (GVHD)

The individual must meet all of the following criteria for initial authorization:
- Is 6 years of age or older;
- Has acute graft-versus-host disease;
- Has tried at least one systemic treatment for GVHD (e.g., cyclosporine, tacrolimus, mycophenolate mofetil, corticosteroids, an etanercept product, Jakafi, Nipent, a tocilizumab product, Entyvio);
- Infliximab intravenous is prescribed by or in consultation with an oncologist, hematologist, or a physician affiliated with a transplant center.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 1 month *(Note: A patient who has received < 1 month of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., normalization of liver function tests, red blood cell count, or platelet count; resolution of fever or rash); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., improvement in skin, oral mucosal, ocular or gastrointestinal symptoms).

Hidradenitis Suppurativa

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Has tried one other therapy (e.g., intralesional or oral corticosteroids, systemic antibiotics, isotretinoin);
- Infliximab intravenous is prescribed by or in consultation with a dermatologist.

The individual must meet all of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 3 months *(Note: A patient who has received < 3 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Hurley staging, Sartorius score, Physician Global Assessment, Hidradenitis Suppurativa Severity Index);
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain or drainage of lesions, nodules, or cysts).

Colitis, Indeterminate

The individual must meet all of the following criteria for initial authorization:
- Is 6 years of age or older;
- Has tried one systemic corticosteroids;
- Has tried mesalamine;
- Has tried either azathioprine or 6-mercaptopurine;
- Infliximab intravenous is prescribed by or in consultation with a gastroenterologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response in at least one objective measure compared to baseline (e.g., fecal markers, serum markers, imaging studies, endoscopic assessment, and/or reduced dose of corticosteroids); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain, fatigue, stool frequency, and/or rectal bleeding).

Juvenile Idiopathic Arthritis

The individual must meet all of the following criteria for initial authorization:
- Is 6 years of age or older;
- Meets one of the following:
    - Has tried one other systemic agent for this condition (e.g., adalimumab, etanercept, methotrexate, non-steroidal anti-inflammatory drug [NSAID]); OR
    - Has aggressive disease;
- Infliximab intravenous is prescribed by or in consultation with a rheumatologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*

- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Physician Global Assessment [MD global], Juvenile Arthritis Disease Activity Score [JDAS], Clinical Juvenile Arthritis Disease Activity Score [cJDAS], Juvenile Spondyloarthritis Disease Activity Index [JSpADA], reduced dosage of corticosteroids, etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., improvement in limitation of motion, less joint pain/tenderness, decreased fatigue, improved function or activities of daily living).

Pyoderma Gangrenosum

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Meets one of the following:
    - Has tried one systemic corticosteroid (e.g., prednisone, methylprednisolone); OR
    - Had a 2-month trial of or intolerance to at least one immunosuppressive agent (e.g., mycophenolate, cyclosporine);
- Infliximab intravenous is prescribed by or in consultation with a dermatologist

The individual must meet all of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 4 months *(Note: A patient who has received < 4 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Has experienced a beneficial clinical response from baseline in at least one of the following: size, depth, and/or number of lesions;
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain and/or tenderness of affected lesions).

Sarcoidosis

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Has tried at least one systemic corticosteroid;
- Has tried at least one immunosuppressive agent (e.g., methotrexate, azathioprine, leflunomide);
- Infliximab intravenous is prescribed by or in consultation with one of the following specialists: pulmonologist, ophthalmologist, cardiologist, neurologist, or dermatologist.

The individual must meet all of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 3 months *(Note: A patient who has received < 3 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*

- Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., lung function, serum markers, improvement in rash or skin manifestations, imaging studies, etc.);
- Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased cough, fatigue, pain, palpitations, and/or shortness of breath).

Scleritis or Sterile Corneal Ulceration

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Has tried one other therapy for this condition (e.g., non-steroidal anti-inflammatory drugs [NSAIDs], methotrexate, cyclosporine, corticosteroids);
- Infliximab intravenous is prescribed by or in consultation with an ophthalmologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., serum markers [e.g., C-reactive protein, erythrocyte sedimentation rate]); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased eye pain, redness, light sensitivity, tearing, and/or improvement in visual acuity).

Still's Disease

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Meets one of the following:
    - Had a 2-month trial of or intolerance to at least one conventional synthetic disease-modifying antirheumatic drug (DMARD) (e.g., methotrexate); OR
    - Had a trial of at least one biologic agent (e.g., Actemra, Arcalyst, Ilaris);
- Has tried one corticosteroid;
- Infliximab intravenous is prescribed by or in consultation with a rheumatologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., resolution of fever, improvement in

rash or skin manifestations, improvement or normalization of serum markers, or reduced dosage of corticosteroids); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain/tenderness, stiffness, or swelling; improved function or activities of daily living).

Spondyloarthritis (SpA), other subtypes

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age or older;
- Meets one of the following:
    - Has arthritis primarily in the knees, ankles, elbows, wrists, hands, and/or feet AND has tried at least one DMARD (e.g., methotrexate, leflunomide, sulfasalazine); OR
    - Has axial spondyloarthritis with objective signs of inflammation, defined as at least one of the following: C-reactive protein elevated beyond the upper limit of normal for the reporting laboratory or sacroilitis reported on magnetic resonance imaging;
- Infliximab intravenous is prescribed by or in consultation with a rheumatologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., Ankylosing Spondylitis Disease Activity Score (ASDAS), serum markers [e.g., C-reactive protein, erythrocyte sedimentation rate]); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased pain or stiffness, improvement in function or activities of daily living).

Uveitis

The individual must meet all of the following criteria for initial authorization:
- Is 6 years of age or older;
- Meets one of the following:
    - Has tried one of the following therapies: periocular, intraocular, or systemic corticosteroids, or immunosuppressive agent; OR
    - Had a trial of either an etanercept product (e.g., Enbrel) or an adalimumab product (e.g., Humira);
- Infliximab intravenous is prescribed by or in consultation with an ophthalmologist.

The individual must meet both of the following criteria for re-authorization:

- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., best-corrected visual acuity, assessment of chorioretinal and/or inflammatory retinal vascular lesions, etc.); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., decreased eye pain, redness, light sensitivity, blurred vision, and/or improvement in visual acuity).

Immunotherapy-Related Toxicities Associated with Checkpoint Inhibitor Therapy

The individual must meet all of the following criteria for initial authorization:
- Is 18 years of age older;
- Developed an immunotherapy-related toxicity other than hepatitis (e.g., gastrointestinal system toxicity, inflammatory arthritis, ocular toxicity);
- Developed the immunotherapy-related toxicity while receiving a checkpoint inhibitor (e.g., Keytruda, Opdivo, Yervoy, Tecentriq, Bavencio, Imfinzi);
- Has tried one systemic corticosteroid (e.g., methylprednisolone, prednisone);
- Infliximab intravenous is prescribed by or in consultation with one of the following specialists: an oncologist, cardiologist, gastroenterologist, hematologist, nephrologist, pulmonologist, rheumatologist, or ophthalmologist.

The individual must meet both of the following criteria for re-authorization:
- Has been established on Infliximab therapy for at least 6 months *(Note: A patient who has received < 6 months of therapy, or who is restarting therapy with an infliximab product, is reviewed under initial authorization criteria.);*
- Meets one of the following:
    - Has experienced a beneficial clinical response from baseline when assessed by at least one objective measure (e.g., improvement or normalization of serum markers [e.g., C-reactive protein, erythrocyte sedimentation rate], fecal markers, and/or reduced dosage of corticosteroids); OR
    - Has experienced an improvement in at least one symptom compared to baseline (e.g., less joint pain/tenderness, stiffness or swelling, stool frequency; improved function of activities of daily living).

Approval duration (initial):
- GVHD: 1 month
- Plaque psoriasis/Behcet's disease/Hidradenitis suppurativa/Sarcoidosis: 3 months
- Pyoderma gangrenosum: 4 months
- All others: 6 months

Approval duration (renewal):

- GVHD: 3 months
- All others: 12 months

Dosing Recommendations

Infliximab is administered by intravenous infusion for at least 2 hours.

Crohn's disease, ulcerative colitis, indeterminate colitis, plaque psoriasis, psoriatic arthritis, hidradenitis suppurativa, and pyoderma gangrenosum
The recommended dose is 5 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

Graft-versus-host disease
The recommended dose is up to 10 mg/kg once weekly.

Rheumatoid arthritis
The recommended dose is 3 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

Ankylosing spondylitis, Behcet's disease, sarcoidosis, and spondyloarthritis
The recommended dose is 5 mg/kg at 0, 2 and 6 weeks, then every 6 weeks.

Uveitis and immunotherapy-related toxicities associated with checkpoint inhibitor therapy
The recommended dose is up to 10 mg/kg at 0, 2 and 6 weeks, then every 4 weeks.

Juvenile idiopathic arthritis and Still's disease
The recommended dose is up to 6 mg/kg at 0, 2 and 6 weeks, then every 8 weeks.

Scleritis or sterile corneal ulceration
The recommended dose is up to 10 mg/kg at 0, 2, 6, and 8 weeks.

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