Market Applicability/Effective Date															
Market	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**IND**	**KS**	**KY**	**LA**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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Remicade (infliximab)

DRUG.00002

Override(s)	Approval Duration
Prior Authorization Step Therapy	1 year

Medications	Comment
Remicade (infliximab)	Intravenous administration

APPROVAL CRITERIA

Remicade (infliximab) **may be approved** for patients who meet the following:

I. Individual has ***none*** of the following:
- **A.** Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections.
- **B.** Individuals who have not had a tuberculin skin test (TST), or a CDC-recommended equivalent, to evaluate for latent tuberculosis.
- **C.** Using in combination with tumor necrosis factor antagonists;
- **D.** Using in combination with the following non-TNF immunomodulatory drugs: abatacept (Orencia), anakinra (Kineret), or tocilizumab (Actemra).

***Note*:** The clinician should consider the status of an individual with moderate or severe heart failure – New York Heart Association (NYHA) Functional Class III-IV before initiating treatment with infliximab at doses >5mg/kg.

AND

II. Diagnosis of Rheumatoid Arthritis (RA) – Individual must meet all of the following:
- **A.** Individual has had a trial and inadequate response or intolerance to TWO preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab) unless the following criteria is met:
  1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) is; **OR**
  2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
     i. Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab); **OR**

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Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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ii. Individual's age; **OR**
iii. Pregnant or planning on becoming pregnant; **OR**
iv. Serious infections or concurrent sepsis; **OR**
v. Other known disease state or medication contraindication which is not also associated with Remicade (infliximab);

AND

B. Individual is 18 years of age or older; **AND**
C. Individual has moderately to severely active RA; **AND**
D. Agent is used for **any** of the following reasons:
1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response; **OR**
3. To inhibit the progression of structural damage; **OR**
4. To improve physical function;

AND

E. Remicade (infliximab) is given in combination with methotrexate or with another immunosuppressive agent if the individual is intolerant to methotrexate; **AND**
F. Individual has failed to respond to, is intolerant of, or has a medical contraindication to one or more non-biologic disease modifying anti-rheumatic drugs (DMARDs);

OR

III. Crohn's Disease (CD) – Individual must meet the following:
A. Individual has had a trial and inadequate response or intolerance to a preferred biologic agent [Current preferred biologic include – Humira (adalimumab) unless the following criteria is met:
1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) is; **OR**
2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
i. Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab); **OR**
ii. Individual's age; **OR**
iii. Pregnant or planning on becoming pregnant; **OR**
iv. Serious infections or concurrent sepsis; **OR**
v. Other known disease state or medication contraindication which is not also associated with Remicade (infliximab);

AND

B. Individual is 6 year of age or older; **AND**

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Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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C. Individual has fistulizing or moderately to severely active CD which has previously responded to therapy with Remicade (infliximab); **OR**

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as 5-Aminosalicylic acid [5-ASA] products, sulfasalazine, systemic corticosteroid, or immunosuppressive drugs) and infliximab is used for one of the following:

1. To reduce signs or symptoms in an individual with moderately to severely active CD; **OR**
2. To induce or maintain clinical remission in an individual with moderately to severely active Crohn's Disease; **OR**
3. To reduce the number of draining enterocutaneous or rectovaginal fistulas in an individual with fistulizing CD of at least 3 months duration.

OR

IV. Ulcerative Colitis (UC) - Individual must meet the following:

A. Individual is 6 years of age or older; **AND**

B. Individual has moderately to severely active ulcerative colitis; **AND**

C. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as 5-ASA products, sulfasalazine, systemic corticosteroids, or immunosuppressive drugs) and infliximab is used for one of the following:

1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical remission and mucosal healing.

OR

V. Active ankylosing spondylitis (AS) – Individual must meet the following:

A. Individual has had a trial and inadequate response or intolerance to TWO preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab) unless the following criteria is met:

1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) is; **OR**
2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   i. Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab); **OR**
   ii. Individual's age; **OR**
   iii. Pregnant or planning on becoming pregnant; **OR**
   iv. Serious infections or concurrent sepsis; **OR**
   v. Other known disease state or medication contraindication which is not also associated with Remicade (infliximab);

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Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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AND

B. Individual is 18 years of age or older; **AND**
C. Individual has active ankylosing spondylitis; **AND**
D. Is used to reduce signs or symptoms of the disease; **AND**
E. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as nonsteroidal anti-inflammatory drugs or non-biologic DMARDs);

OR

VI. Active psoriatic arthritis (PsA) – Individual must meet the following:

A. Individual has had a trial and inadequate response or intolerance to TWO preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab) unless the following criteria is met:
1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) is; **OR**
2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   i. Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab); **OR**
   ii. Individual's age; **OR**
   iii. Pregnant or planning on becoming pregnant; **OR**
   iv. Serious infections or concurrent sepsis; **OR**
   v. Other known disease state or medication contraindication which is not also associated with Remicade (infliximab);

AND

B. Individual is 18 years of age or older; **AND**
C. Individual has active psoriatic arthritis; **AND**
D. Agent is used for **any** of the following reasons:
1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response; **OR**
3. To inhibit the progression of structural damage; **OR**
4. To improve physical function;

AND

E. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as non-biologic DMARDs);

OR

Market Applicability/Effective Date															
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Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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VII. Plaque psoriasis (Ps) – Individual must meet the following:

A. Individual has had a trial and inadequate response or intolerance to TWO preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab) unless the following criteria is met:

1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) is; **OR**
2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   i. Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab); **OR**
   ii. Individual's age; **OR**
   iii. Pregnant or planning on becoming pregnant; **OR**
   iv. Serious infections or concurrent sepsis; **OR**
   v. Other known disease state or medication contraindication which is not also associated with Remicade (infliximab);

AND

B. Individual is 18 years of age or older; **AND**

C. Agent is used for **any** of the following reasons:

1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response;

AND

D. Individual has failed to respond to, is intolerant of, or has a medical contraindication to the use of phototherapy or other systemic therapies (such as methotrexate, acitretin, or cyclosporine); **AND**

E. Diagnosis of chronic moderate to severe plaque psoriasis with EITHER of the following:

1. Plaque psoriasis involving greater than 5% of body surface area (BSA); **OR**
2. Plaque psoriasis involving less than or equal to 5% body surface area involving sensitive areas or areas that would significantly impact daily function (such as palms, soles of feet, head/neck, or genitalia)

OR

VIII. Juvenile Idiopathic Arthritis (JIA) when all of the following are met:

A. Individual is 2 years of age or older with moderately to severely active JIA; **AND**

B. Agent is used for **any** of the following reasons:

1. To reduce signs or symptoms; **OR**
2. To induce or maintain clinical response;

Market Applicability/Effective Date															
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Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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AND

C. Individual has failed to respond to , is intolerant of, or has a medical contraindication to one or more nonbiologic DMARDs

OR

IX. Non-infectious Uveitis when each of the following criteria are met:

A. Individual has chronic, recurrent, treatment-refractory or vision-threatening disease; **AND**

B. Individual has failed to respond to, is intolerant of, or has a medical contraindication to conventional therapy (such as corticosteroids or immunosuppressive drugs [for example, azathioprine, cyclosporine, or methotrexate]).

Infliximab is considered **investigational and may NOT be approved** when the above criteria are not met and for all other indications, including, but not limited to treatment of asthma, chronic obstructive pulmonary disease, disc-herniation-induced sciatica, hairy cell leukemia, graft-versus-host disease (GVHD), hidradenitis suppurativa, acute Kawasaki disease, neurosarcoidosis, sarcoidosis, Still's disease, Sjörgren's syndrome, Takayasu arteritis, and Wegener's granulomatosis.

Note: Remicade (infliximab) has a black box warning related to the increased risk of developing serious infections that could result in hospitalization or death. Individuals should be closely monitored for the development of infection during and after treatment with discontinuation of therapy if the individual develops a serious infection or sepsis. Reported infections include: Tuberculosis, invasive fungal infections (including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis), and infections (bacterial, viral, or other) due to opportunistic pathogens (including Legionella and Listeria). The risks and benefits of treatment with Remicade should be considered prior to initiating in individuals with chronic or recurrent infection. Remicade is not indicated for the use in pediatric individuals due to reports of lymphoma and other malignancies developing in children and adolescents treated with tumor necrosis factor (TNF) blockers.

Market Applicability/Effective Date															
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Applicable	X	NA	NA	X	X	NA	X	X	X	X	X	X	NA	NA	X

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State Specific Mandates		
N/A	N/A	N/A

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