Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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Inflectra (infliximab-dyyb), Remicade (infliximab), Renflexis (infliximab-abda),

CG-DRUG-64, CG-DRUG-65

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Inflectra (infliximab-dyyb) Remicade (infliximab) Renflexis (infliximab-abda)

APPROVAL CRITERIA

Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) may be approved the following criteria are met:

I. Diagnosis of Crohn's Disease:
   A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to a ONE (1) preferred biologic agent [Current preferred biologics include – Humira (adalimumab), Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda)] unless the following criteria is met:
      1. Individual has been receiving and is maintained on a stable dose of Remicade (infliximab); **OR**
      2. The preferred agents are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Remicade (infliximab) does; **OR**
      3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab); **OR**
         b. Individual's age; **OR**
         c. Pregnant or planning on becoming pregnant; **OR**
         d. Serious infections or concurrent sepsis; **OR**
      4. The preferred agent(s) do not have activity against a concomitant clinical condition and Remicade (infliximab) does. Examples include but may not be limited to the following:

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred;

AND

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

C. Individual has fistulizing or moderately to severely active Crohn's Disease which has previously responded to therapy with Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **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, infliximab-dyyb, or infliximab-abda is used for one of the following:
1. To reduce signs or symptoms in an individual with moderately to severely active Crohn's Disease; **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 Crohn's Disease of at least 3 months duration.

OR

II. Diagnosis of Ulcerative Colitis:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to ONE (1) preferred biologic agent [Current preferred biologic include – Humira (adalimumab) , Inflectra (infliximab-dyyb) or Renflexis (infliximab-abda)] unless the following criteria is met:
1. Individual has been receiving and is maintained on a stable dose of Remicade (infliximab); **OR**
2. The preferred agents are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Remicade (infliximab) does ; **OR**
3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
a. Known hypersensitivity to any active or inactive component which is not also associated with the requested agent Remicade (infliximab); **OR**
b. Individual's age; **OR**
c. Pregnant or planning on becoming pregnant; **OR**
d. Serious infections or concurrent sepsis; **OR**
4. The preferred agent(s) do not have activity against a concomitant clinical condition Remicade (infliximab) does. Examples include but may not be limited to the following:
a. Concomitant Psoriasis: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
b. Concomitant Rheumatoid Arthritis: TNFi agents are preferred;

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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AND

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

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

D. 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, infliximab-dyyb, or infliximab-abda 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

III. Diagnosis of Rheumatoid Arthritis:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as 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. Individual has been receiving and is maintained on a stable dose of Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   a. Known hypersensitivity to any active or inactive component which is not also associated with Inflectra (infliximab- dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
   b. Individual's age; **OR**
   c. Pregnant or planning on becoming pregnant; **OR**
   d. Serious infections or concurrent sepsis; **OR**
3. The preferred agent(s) do not have activity against a concomitant clinical condition and Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) does. An example includes but may not be limited to the following:
   a. Concomitant Crohn's disease: TNFi (agents FDA-approved for both indications) are preferred; **AND**

B. Individual is 18 years of age or older;

AND

C. Individual has moderately to severely active Rheumatoid 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. Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) is given in combination with methotrexate or with another immunosuppressive agent if

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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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

IV. Diagnosis of Ankylosing spondylitis:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to TWO (2) preferred biologic agents [Current preferred biologics include – Enbrel (etanercept) and Humira (adalimumab)] unless the following criteria is met:

1. Individual has been receiving and is maintained on a stable dose of Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
2. The preferred agents are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) does; **OR**
3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   a. Known hypersensitivity to any active or inactive component which is not also associated with Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
   b. Individual's age; **OR**
   c. Pregnant or planning on becoming pregnant; **OR**
   d. Serious infections or concurrent sepsis;

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

V. Diagnosis of Psoriatic arthritis:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as 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. Individual has been receiving and is maintained on a stable dose of Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
2. The preferred agents are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) does;

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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OR

3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   a. Known hypersensitivity to any active or inactive component which is not also associated with Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
   b. Individual's age; **OR**
   c. Pregnant or planning on becoming pregnant; **OR**
   d. Serious infections or concurrent sepsis; **OR**
4. The preferred agent(s) do not have activity against a concomitant clinical condition and Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) does. Examples include but may not be limited to the following:
   a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
   b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred;

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

VI. Diagnosis of Plaque psoriasis (Psoriasis vulgaris):
   A. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as 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. Individual has been receiving and is maintained on a stable dose of Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
      2. The preferred agents are not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) does; **OR**
      3. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
         a. Known hypersensitivity to any active or inactive component which is not also associated with the requested agent [Inflectra (infliximab-dyyb), Remicade

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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(infliximab), or Renflexis (infliximab-abda)]; **OR**

b. Individual's age; **OR**

c. Pregnant or planning on becoming pregnant; **OR**

d. Serious infections or concurrent sepsis; **OR**

4. The preferred agent(s) do not have activity against a concomitant clinical condition and the requested non-preferred agent does. Examples include but may not be limited to the following:
   a. Concomitant Crohn's Disease: TNFi (agents FDA-approved for both indications) or Stelara are preferred; **OR**
   b. Concomitant Ulcerative Colitis: TNFi (agents FDA-approved for both indications) are preferred;

AND

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

C. Diagnosis of chronic moderate to severe plaque psoriasis (psoriasis vulgaris) with EITHER of the following:
   1. Plaque psoriasis (psoriasis vulgaris) involving greater than 5% of body surface area ; **OR**
   2. Plaque psoriasis (psoriasis vulgaris) 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)

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;

AND

E. 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);

OR

VII. Diagnosis of Juvenile Idiopathic Arthritis:

A. Individual is 2 years of age or older with moderately to severely active juvenile idiopathic arthritis; **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;

AND

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

OR

VIII. Diagnosis of Non-infectious Uveitis:

A. Individual has had a trial (medication samples/coupons/discount cards are excluded

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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from consideration as a trial) and inadequate response or intolerance to the preferred biologic agent, Humira (adalimumab), unless the following criteria is met:

1. Individual has been receiving and is maintained on a stable dose of Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
2. The preferred agent is not FDA approved and do not have an accepted off-label use per the off-label policy for the prescribed indication and Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) does; **OR**
3. The preferred agent is not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:
   a. Known hypersensitivity to any active or inactive component which is not also associated with Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda); **OR**
   b. Individual's age; **OR**
   c. Pregnant or planning on becoming pregnant; **OR**
   d. Serious infections or concurrent sepsis;

AND

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

C. 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]);

OR

IX. Immune checkpoint inhibitor therapy-related toxicities (grade 3 or grade 4 adverse events)* in an individual with any of the following conditions:

A. Severe or life-threatening diarrhea or colitis unresponsive to high-dose systemic corticosteroids; **OR**

B. Severe or life-threatening pneumonitis if no improvement after 48 hours of high-dose systemic corticosteroids; **OR**

C. Severe or life-threatening renal failure or elevated serum creatinine (that is, greater than 3 times baseline or greater than 4.0 mg/dL) if toxicity remains greater than grade 2 after 1 week of corticosteroids; **OR**

D. Severe or life-threatening cardiovascular adverse events (such as, arrhythmias, impaired ventricular function, myocarditis, or pericarditis); **OR**

E. Severe or life-threatening inflammatory arthritis unresponsive to corticosteroids or anti-inflammatory agents.

*Note: See Definitions for grade 3 and grade 4 adverse events

Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) may **not** be approved for an individual with the following:

Market Applicability														
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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I. In combination with other TNF antagonists; **OR**
II. In combination with tofacitinib citrate (Xeljanz); **OR**
III. In combination with the following non-TNF immunomodulator drugs: abatacept (Orencia), anakinra (Kineret), tocilizumab (Actemra), or vedolizumab (Entyvio); **OR**
IV. Tuberculosis, invasive fungal infection, other active serious infections, or a history of recurrent infections; **OR**
V. Individual has not had a tuberculin skin test or a Centers for Disease Control and Prevention (CDC)-recommended equivalent, to evaluate for latent tuberculosis prior to initiating therapy; **OR**
VI. 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: 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, infliximab-dyyb, or infliximab-abda at doses >5mg/kg.

*Grading systems for immune checkpoint inhibitor-related adverse events (severe: grade 3 [G3]; life-threatening: grade 4 [G4]):

- Gastrointestinal (diarrhea and colitis): The Common Terminology Criteria for Adverse Events (v5.0) grading system is most often used to clinically define grades of diarrhea/colitis as follows:
  - Grade 3: Increase of 7 or more stools per day over baseline, incontinence, hospitalization indicated, severe increase in ostomy output compared with baseline, limiting self-care ADLs;
  - Grade 4: Life-threatening consequences; urgent intervention indicated.
- Lung (pneumonitis) (Brahmer, 2018):
  - Grade 3: Severe symptoms, hospitalization required, involves all lung lobes or greater than 50% of lung parenchyma, limiting self-care ADL, oxygen indicated;
  - Grade 4: Life-threatening respiratory compromise, urgent intervention indicated (intubation).
- Renal (renal failure or elevated serum creatinine) (Brahmer, 2018; NCCN CPG, V1.2018):
  - Grade 3: Creatinine greater than 3 times baseline or greater than 4.0 mg/dL, hospitalization indicated;
  - Grade 4: Life-threatening consequences, creatinine greater than 6 times baseline, dialysis indicated.
- Cardiovascular (arrhythmias, impaired ventricular function, myocarditis, or pericarditis) (Brahmer, 2018; NCCN CPG V1.2018):
  - Grade 3: Moderate to severely abnormal testing or symptoms with mild activity, including arrhythmia, significant echocardiogram findings without hypotension, abnormal cardiac markers (greater than upper limit of normal [ULN]);

Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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  - Grade 4: Moderate to severe decompensation, arrhythmia, hemodynamic (hypotension/cardiomyopathy) greater than 3 times ULN, IV medication or intervention required, life-threatening symptoms.
- Musculoskeletal (inflammatory arthritis) (Brahmer, 2018; NCCN CPG V1.2018):
  - Grade 3-4: Severe pain associated with signs of inflammation, erythema, or joint swelling, with or without irreversible joint damage, disabling, limiting self-care ADLs.

Note: Inflectra (infliximab-dyyb), Remicade (infliximab), or Renflexis (infliximab-abda) have 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 Inflectra, Remicade, or Renflexis should be considered prior to initiating in individuals with chronic or recurrent infection. Inflectra, Remicade, and Renflexis are 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.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

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Market Applicability														
Market	**DC**	**FL & FHK**	**FL MMA**	**FL LTC**	**GA**	**KS**	**KY**	**MD**	**NJ**	**NV**	**NY**	**TN**	**TX**	**WA**
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	NA	NA	NA

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