**Infliximab/Infliximab-dyyb**  
**DRUG.00002**

### Override(s)

<table>
<thead>
<tr>
<th>Override(s)</th>
<th>Approval Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>1 year</td>
</tr>
<tr>
<td>Step Therapy</td>
<td></td>
</tr>
</tbody>
</table>

### Medications

<table>
<thead>
<tr>
<th>Medications</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Remicade (infliximab)</td>
<td>Intravenous administration</td>
</tr>
<tr>
<td>Inflectra (inflectra-dyyb)</td>
<td>Intravenous administration</td>
</tr>
</tbody>
</table>

### APPROVAL CRITERIA

Remicade (infliximab) or Inflectra (infliximab-dyyb) **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 prior to initiating infliximab or infliximab-dyyb;
   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);
   E. Using in combination with tofacitinib citrate (Xeljanz).

**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:

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*FHK- Florida Healthy Kids*
Market Applicability/Effective Date

<table>
<thead>
<tr>
<th>Market</th>
<th>FL &amp; FHK</th>
<th>FL MMA</th>
<th>FL LTC</th>
<th>GA</th>
<th>KS</th>
<th>KY</th>
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<tr>
<td>Applicable</td>
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</tr>
</tbody>
</table>

*FHK- Florida Healthy Kids

1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) or Inflectra (infliximab-dyyb) 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 Inflectra (infliximab-dyyb); 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) or Inflectra (infliximab-dyyb);

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) or Inflectra (infliximab-dyyb) 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) or Inflectra (infliximab-dyyb) is; OR
   2. The preferred agents are not acceptable due to concomitant clinical conditions, such as but not limited to any of the following:

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.
### Market Applicability/Effective Date

| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|--------|---------|--------|--------|----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

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- Known hypersensitivity to any active or inactive component which is not also associated with Remicade (infliximab) or Inflectra (infliximab-dyyb); **OR**
- Individual's age; **OR**
- Pregnant or planning on becoming pregnant; **OR**
- Serious infections or concurrent sepsis; **OR**
- Other known disease state or medication contraindication which is not also associated with Remicade (infliximab) or Inflectra (infliximab-dyyb);

**AND**

- Individual is 6 year of age or older; **AND**
- Individual has fistulizing or moderately to severely active CD which has previously responded to therapy with Remicade (infliximab) or Inflectra (infliximab-dyyb); **OR**
- 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 or infliximab-dyyb 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:

- Individual is 6 years of age or older; **AND**
- Individual has moderately to severely active ulcerative colitis; **AND**
- 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 or infliximab-dyyb 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:

- 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:

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| Market | FL & FHK | FL MMA | FL LTC | GA | KS | KY | LA | MD | NJ | NV | NY | TN | TX | WA |
|-------|---------|-------|-------|----|----|----|----|----|----|----|----|----|----|----|----|
| Applicable | X | NA | NA | X | NA | X | X | X | X | X | X | NA | NA | X |

*FHK- Florida Healthy Kids

1. The preferred agents are not FDA approved for the prescribed indication and Remicade (infliximab) or Inflectra (infliximab-dyyb) 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 Inflectra (infliximab-dyyb); **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) or Inflectra (infliximab-dyyb);

**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) or Inflectra (infliximab-dyyb) 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 Inflectra (infliximab-dyyb); **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) or Inflectra (infliximab-dyyb);

**AND**

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