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INFLIXIMAB Infusions - MB9231

RENFLEXIS (infliximab-abda)
INFLECTRA (infliximab-dyyb)
REMICADE (infliximab)

Covered Service: Yes–when meets criteria below

Prior Authorization Required: Yes–as shown below

Additional Information: 

RENFLEXIS is the preferred infliximab product. Use of a different infliximab product will be not covered. In addition to the criteria below, coverage of REMICADE or INFLECTRA requires a trial failure of RENFLEXIS. Must be prescribed by dermatology, rheumatology, or gastroenterology specialists with prior authorization through Navitus.

Medicare Policy:

Prior authorization is dependent on the member’s Medicare coverage. Prior authorization is not required for Medicare Cost products (Dean Care Gold) and Medicare Supplement (Select) when this drug is provided by participating providers. Prior authorization is required if a member has Medicare primary and Dean Health Plan secondary coverage. This policy is not applicable to our Medicare Replacement product (Dean Advantage).

BadgerCare Plus Policy:

Dean Health Plan covers this benefit when BadgerCare Plus also covers the benefit. Please refer to Forward Health: https://www.forwardhealth.wi.gov/WIPortal/Default.aspx

Dean Health Plan Approved Criteria:

1.0 RENFLEXIS is the preferred infliximab product. Use of a different infliximab product will be not covered. In addition to the criteria below, coverage of REMICADE or INFLECTRA requires a trial failure of RENFLEXIS.

2.0 For moderate to severe rheumatoid arthritis (RA), it is considered medically necessary when all of the following criteria are met:

   2.1 Prescribed by a rheumatology specialist; and

   2.2 18 years of age or older; and
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2.3 Failed a trial of one or more conventional DMARD alone (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, corticosteroids) or in combination, and must have included methotrexate ≥ 20mg/week for at least 8 weeks, and

2.4 No response after 3 months of therapy (no change in CDAI score), or member did not reach goal at 6 months (goal is defined as remission, CDAI score of 0.0-2.8) or low disease activity (CDAI score of 2.9-10.0), and

2.5 Concurrent treatment with methotrexate.

3.0 For moderate to severe juvenile idiopathic arthritis, it is considered medically necessary when all of the following criteria are met:

3.1 Prescribed by a rheumatology specialist; and

3.2 Failed a trial of one or more conventional DMARD alone (e.g. methotrexate, sulfasalazine, hydroxychloroquine, leflunomide, corticosteroids) or in combination, and must have included methotrexate ≥ 20mg/week for at least 8 weeks, and

3.3 No response after 3 months of therapy (no change in CDAI score), or member did not reach goal at 6 months (goal is defined as remission, CDAI score of 0.0-2.8) or low disease activity (CDAI score of 2.9-10.0), and

3.4 Concurrent treatment with methotrexate.

4.0 For predominantly axial involvement in active ankylosing spondylitis (AS) or other active spondyloarthropathies or psoriatic arthritis (PsA), it is considered medically necessary when all of the following criteria are met:

4.1 Prescribed by a rheumatology specialist; and

4.2 18 years of age or older;

5.0 For predominantly peripheral involvement in active ankylosing spondylitis (AS) or other active spondyloarthropathies, or psoriatic arthritis (PsA), it is considered medically necessary when all of the following criteria are met:

5.1 Prescribed by a rheumatology specialist; and

5.2 18 years of age or older;

5.3 Failure of 3 or more months of therapy with each of 2 or more different NSAIDs; and

5.4 Failure of 4 or more months therapy of sulfasalazine or methotrexate.

6.0 For moderate to severe plaque psoriasis (PPsor), it is considered medically necessary when all of the following criteria are met:

6.1 Prescribed by a dermatology specialist; and
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6.2 18 years of age or older; and
6.3 Ten percent or more involvement of the body surface area; and
6.4 Significant functional disability; and
6.5 Failure of other treatments including:
   6.5.1 Topical agents (corticosteroids, coal tars, calcipotriene, tazarotene and anthralin); or
   6.5.2 Immunosuppressive (cyclosporine, methotrexate, phototherapy); or
   6.5.3 Photochemotherapy (psoralen plus ultraviolet A therapy);
6.6 No concomitant systemic therapy or phototherapy.

7.0 For Crohn’s disease (CD), it is considered medically necessary when the following criteria are met:
   7.1 Prescribed by a gastroenterology specialist; and
   7.2 Fistulizing Crohn’s disease in patients 18 years of age or older with draining enterocutaneous or rectovaginal fistula lasting 3 or more months; or
   7.3 Moderate to severe Crohn’s Disease in patients 6 years of age or older who had an inadequate response to conventional therapy.

8.0 For moderate to severe ulcerative colitis (UC), it is considered medically necessary when all of the following criteria are met:
   8.1 Prescribed by a gastroenterology specialist; and
   8.2 18 years of age or older; and
   8.3 Failure of conventional therapy which includes oral corticosteroids, 6-mercaptopurine, azathioprine and salicylates.

9.0 For hidradenitis suppurativa (HS), it is considered medically necessary when all of the following criteria are met:
   9.1 Prescribed by a dermatology specialist; and
   9.2 Defined as total abscesses or inflammatory nodule count of ≥ 3; and
   9.3 Tried and failed at least one (1) oral antibiotic (documentation including trial and dates is required)

Comments:

1.0 FDA Boxed Warnings are listed below to be used as a guide when evaluating infliximab’s risk versus benefit. See full prescribing information for details.
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1.1 Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.

1.2 Discontinue infliximab if a patient develops a serious infection.

1.3 Perform test for latent TB; if positive, start treatment for TB prior to starting infliximab. Monitor all patients for active TB during treatment, even if initial latent TB test is negative.

1.4 Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab.

1.5 Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF blockers including infliximab. All infliximab cases were reported in patients with Crohn’s disease or ulcerative colitis, the majority of whom were adolescent or young adult males. All had received azathioprine or 6-mercaptopurine concomitantly with infliximab at or prior to diagnosis.

2.0 Initial infusion and duration limits as follows:

2.1 RA and JIA: Maximum of 5 infusions in a 6 month period

2.2 AS, PPsor, PsA, UC, CD: Maximum of 4 infusions in a 4 month period

2.2.1 NOTE – CD patients who do not respond by week 14 are unlikely to respond to continued dosing and may be ineligible for continued coverage

3.0 Most medications have a maximum dosage and are proven when used according to labeled indications or when otherwise supported by published clinical evidence.

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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| RA, JIA     | Induction: 3 mg/kg IV at weeks 0, 2, and 6  
             Maintenance: 3 mg/kg IV every 8 weeks  
             Incomplete response: 10 mg/kg IV every 8 weeks; or 3 mg/kg every 4 weeks |
| AS          | Induction: 5 mg/kg IV at weeks 0, 2, and 6  
             Maintenance: 5 mg/kg IV every 6 weeks |
| PPsor, PsA, UC, HS | Induction: 5 mg/kg IV at weeks 0, 2, and 6  
                             Maintenance: 5 mg/kg IV every 8 weeks |
| CD          | Induction: 5 mg/kg IV at weeks 0, 2, and 6  
             Maintenance 5 mg/kg IV every 8 weeks  
             For ADULT patients who respond and then lose response, consideration may be given to treatment with 10 mg/kg IV every  |
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| 8 weeks. Patients who do not respond by week 14 are unlikely to respond and may be ineligible for continued coverage. |

4.0 Continuation of therapy limits and criteria:

4.1 RA and JIA: After initial 6 months of therapy, a maximum of 7 infusions in a 1 year period may be considered medically necessary when documentation (including chart notes) indicate that there is disease stability or improvement. Examples of improvement include laboratory assessment (e.g. CRP, ESR, anemia improvement), and symptomatic improvements (e.g. fatigue, function, HAQ score, joint pain).

4.2 AS: After initial 4 months of therapy, a maximum of 8 infusions in a 1 year period may be considered medically necessary when documentation (including chart notes) indicate that there is disease stability or improvement. Examples of improvement include laboratory assessment (e.g. CRP, ESR, anemia improvement), and symptomatic improvements (e.g. fatigue, function, HAQ score, joint pain).

4.3 PPsor, HS: After initial 4 months of therapy, a maximum of 7 infusions in a 1 year period may be considered medically necessary when documentation (including chart notes) indicate that there is significant and sustained clinical improvement. Examples of improvement include PASI, PGA, and BSA affected.

4.4 PsA: After initial 4 months of therapy, a maximum of 7 infusions in a 1 year period may be considered medically necessary when documentation (including chart notes) indicate that there is significant and sustained clinical improvement. Examples of improvement include laboratory assessment (e.g. CRP, ESR, anemia improvement), and symptomatic improvements (e.g. fatigue, function, HAQ score, joint pain).

4.5 UC, CD: After initial 4 months of therapy, a maximum of 7 infusions in a 1 year period may be considered medically necessary when documentation (including chart notes) indicate that there is significant and sustained clinical improvement. Examples of improvement include laboratory assessment (e.g. CRP, hemoglobin, ESR, WBC, albumin), symptom assessment (e.g. bleeding, stooling pattern, abdominal pain, extraintestinal complaints, fatigue), and endoscopy results.

5.0 Dean Health Plan considers all other indications from those listed above as experimental and investigational and are not covered.

6.0 The following information must be presented for each claim submitted for payment or coverage for such claims WILL BE DENIED:

6.1 NDC
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6.2 NDC Label Name
6.3 Total Quantity
6.4 Unit of Measure (mL, mg, gm)

7.0 Coding specifications*
*Codes and descriptors listed below are provided for informational purposes only and may not be all inclusive or current. Listing of a code in this drug policy does not imply that the service described by the code is a covered or non-covered service. Benefit coverage for any service is determined by the member’s policy of health coverage with Dean Health Plan, Inc. Inclusion of a code in the table below does not imply any right to reimbursement or guarantee claim payment. Other drug or medical policies may also apply.

7.1 NDC and HCPCS codes

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<th>How Supplied</th>
<th>National Drug Code (NDC)</th>
<th>HCPCS code</th>
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<td>RENFLEXIS</td>
<td>Infliximab-abda 100mg/vial single dose vial</td>
<td>00006-4305-01             Q5102</td>
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8.0 NOTE: The use of physician samples or manufacturer discounts does not guarantee later coverage under the provisions of the medical certificate and/or pharmacy benefit. All criteria must be met in order to obtain coverage of the listed drug product.

Committee/Source Date(s)
Originated: Utilization Management Committee/ P&T Committee August 9, 2000
Revised:  Utilization Management Committee/Medical Affairs November 12, 2003
           Utilization Management Committee/Medical Affairs/Navitus PBM August 10, 2005
           Utilization Management Committee/Medical Affairs/ GI Clinicians/Drug TA Subcommittee June 14, 2006
           Medical Director Committee/Medical Affairs January 27, 2011
           Medical Director Committee/Medical Affairs August 21, 2013
           Medical Director Committee/Medical Affairs July 16, 2014
           Medical Director Committee/Medical Affairs October 21, 2015
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Effective: 10/01/2017
Published: 10/01/2017