# Clinical Policy: Infliximab

Reference Number: QCP.PHAR.003
Date of Last Revision: 05.24

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

**Description**
Infliximab-axxq (Avsola®), infliximab-dyyb (Inflectra®), infliximab (Remicade®), infliximab-abda (Renflexis®) are immunosuppressive drugs.

**Policy/Criteria**
**I. Initial Approval Criteria**
A. Axial Spondyloarthritis (must meet all)
1. Diagnosis of AS or nr-axSpA;
2. Request is for one of the following: Avsola, Inflectra, Remicade, or Renflexis,
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Failure of at least TWO non-steroidal anti-inflammatory drugs (NSAIDs) at up to maximally indicated doses, each used for at ≥ 4 weeks unless contraindicated or clinically significant adverse effects are experienced;
6. For AS, one of the following (a, or b)
    a. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (i and ii):
        i. Inflectra and Renflexis;
        ii. If member has failed Inflectra and Renflexis, then member must use Avsola;
    b. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
7. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
8. Dose does not exceed maximum dose indicated in Section V.
**Maximum dose escalation allowed per prescriber information with documentation of inadequate response.*

Approval duration: 6 months

B. Crohn's Disease (must meet all):
1. Diagnosis of CD;
2. Request is for one of the following: Avsola, Inflectra, Remicade, or Renflexis
3. Prescribed by or in consultation with a gastroenterologist;
4. Member meets one of the following (a or b):

a. Failure of a ≥ 3 consecutive month trial of at least ONE immunomodulator (e.g., azathioprine, 6-mercaptopurine [6-MP], methotrexate [MTX]) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
b. Medical justification supports inability to use immunomodulators (see Appendix E);

5. age ≥ 6 years;
6. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Inflectra and Renflexis;
   b. If member has failed Inflectra and Renflexis, then member must use Avsola;
7. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
9. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

C. Kawasaki Disease (off-label) (must meet all):

1. Diagnosis of Kawasaki disease;
2. Request is for an infliximab-containing product;
3. Prescribed by or in consultation with a cardiologist, allergist, immunologist, infectious disease specialist, or rheumatologist;
4. Age ≥ 6 years;
5. Failure of immune globulins (Gammagard is preferred), unless contraindicated or clinically significant adverse effects are experienced;
6. If request is for Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Inflectra and Renflexis;
   b. If member has failed Inflectra and Renflexis, then member must use Avsola;
7. If request is for Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
8. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
9. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 4 weeks (one time approval)

D. Plaque Psoriasis (must meet all):

1. Diagnosis of PsO and Request is for Avsola, Inflectra, Remicade, or Renflexis: PsO is chronic-severe as evidenced by involvement of one of the following (i or ii):

i. ≥ 10% of total body surface area;
ii. Hands, feet, scalp, face, or genital area;

1. Prescribed by or in consultation with a dermatologist or rheumatologist;
2. Age ≥ 18 years;
3. Member has moderate-to-severe disease, and one of the following (i, ii, or iii):
   i. Failure of a ≥ 3 consecutive months trial of methotrexate (MTX) at up to maximally indicated doses;
   ii. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a ≥ 3 consecutive months trial of cyclosporine or acitretin at up to maximally indicated doses, unless clinically significant adverse effects are experienced or both are contraindicated;
   iii. Member has intolerance or contraindication to MTX, cyclosporine, and acitretin, and failure of phototherapy, unless contraindicated or clinically significant adverse effects are experienced;
4. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Inflectra and Renflexis;
   b. If member has failed Inflectra and Renflexis, then member must use Avsola;
5. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
6. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
7. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

E. Psoriatic Arthritis (must meet all):

1. Diagnosis of PsA;
2. Request is for one of the following: Avsola, Inflectra, Remicade, or Renflexis
3. Prescribed by or in consultation with a dermatologist or rheumatologist;
4. Age ≥ 18 years;
5. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
   a. Inflectra and Renflexis;
   b. If member has failed Inflectra and Renflexis, then member must use Avsola;
6. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
7. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
8. Dose does not exceed maximum dose indicated in Section V.

**Maximum dose escalation allowed per prescriber information with documentation of inadequate response.*

Approval duration: 6 months

F. Rheumatoid Arthritis (must meet all):

1. Diagnosis of RA per ACR criteria (see Appendix H);
2. Request is for one of the following: Avsola, Inflectra, Remicade, or Renflexis
3. Prescribed by or in consultation with a rheumatologist;
4. Age ≥ 18 years;
5. Member meets one of the following (a or b):
    a. Failure of a ≥ 3 consecutive months trial of MTX at up to maximally indicated doses;
    b. Member has intolerance or contraindication to MTX (see Appendix D), and failure of a ≥ 3 consecutive months trial of at least ONE conventional DMARD (e.g., sulfasalazine, leflunomide, hydroxychloroquine) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;
6. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
    a. Inflectra and Renflexis;
    b. If member has failed Inflectra and Renflexis, then member must use Avsola;
7. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis
8. Documentation of one of the following baseline assessment scores (a or b):
9. Clinical disease activity index (CDAI) score (see Appendix I);
10. Routine assessment of patient index data 3 (RAPID3) score (see Appendix J);
11. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
12. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

G. Ulcerative Colitis (must meet all):

1. Diagnosis of UC;
2. Request is for one of the following: Avsola, Inflectra, Remicade, or Renflexis
3. Prescribed by or in consultation with a gastroenterologist;
4. Documentation of a Mayo Score ≥ 6 (see Appendix F);
5. Age ≥ 6 years;
6. Failure of an 8-week trial of systemic corticosteroids, unless contraindicated or clinically significant adverse effects are experienced;
7. For Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):

a. Inflectra and Renflexis;
b. If member has failed Inflectra and Renflexis, then member must use Avsola;

8. For Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
9. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
10. Dose does not exceed maximum dose indicated in Section V.

Approval duration: 6 months

**II. Continued Therapy**

A. Kawasaki Disease (off-label) (must meet all):
1. Re-authorization for infliximab is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. All Other Indications in Section I (must meet all):
1. Member Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member meets one of the following (a, or b):
    a. For RA: Member is responding positively to therapy as evidenced by one of the following (i or ii):
        i. A decrease in CDAI (see Appendix I) or RAPID3 (see Appendix J) score from baseline;3. member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors
        ii. Medical justification stating inability to conduct CDAI re-assessment, and submission of RAPID3 score associated with disease severity that is similar to initial CDAI assessment or improved;
    b. For all other indications: Member is responding positively to therapy;
3. If request is for Remicade, member must use ALL of the following, unless clinically significant adverse effects are experienced or all are contraindicated (a and b):
    a. Inflectra and Renflexis;
    b. If member has failed Inflectra and Renflexis, then member must use Avsola;
4. If request is for Avsola, member must use BOTH of the following, unless clinically significant adverse effects are experienced or both are contraindicated: Inflectra and Renflexis;
5. Member does not have combination use of biological disease-modifying antirheumatic drugs or JAK inhibitors (see Section III: Diagnoses/Indications for which coverage is NOT authorized);
6. If request is for a dose increase, new dose does not exceed maximum dose indicated in Section V.

Approval duration: 12 months

**III. Diagnoses/Indications for which coverage is NOT authorized:**

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – HIM.PA.154 for health insurance marketplace or evidence of coverage documents;

B. Combination use of biological disease-modifying antirheumatic drugs (bDMARDs) or potent immunosuppressants, including but not limited to any tumor necrosis factor (TNF) antagonists [e.g., Cimzia®, Enbrel®, Humira® and its biosimilars, Simponi®, Avsola™, Inflectra™, Remicade®, Renflexis™], interleukin agents [e.g., Arcalyst® (IL-1 blocker), Ilaris® (IL-1 blocker), Kineret® (IL-1RA), Actemra® (IL-6RA), Kevzara® (IL-6RA), Stelara® (IL-12/23 inhibitor), Cosentyx® (IL-17A inhibitor), Taltz® (IL-17A inhibitor), Siliq™ (IL-17RA), Ilumya™ (IL-23 inhibitor), Skyrizi™ (IL-23 inhibitor), Tremfya® (IL23 inhibitor)], Janus kinase inhibitors (JAKi) [e.g., Xeljanz®/Xeljanz® XR, Cibinqo™, Olumiant™, Rinvoq™], anti-CD20 monoclonal antibodies [Rituxan®, Riabni™, Ruxience™, Truxima®, Rituxan Hycela®], selective co-stimulation modulators [Orencia®], and integrin receptor antagonists [Entyvio®] because of the additive immunosuppression, increased risk of neutropenia, as well as increased risk of serious infections

**IV. Appendices/General Information**

**Appendix A:** Abbreviation/Acronym Key

ACR: American College of Rheumatology
AS: ankylosing spondylitis
CD: Crohn's disease
CDAI: clinical disease activity index
DMARDs: disease-modifying antirheumatic drugs
EULAR: European Union League Against Rheumatism
JAK: Janus kinase
MTX: methotrexate
nr-axSpA: non-radiographic axial spondyloarthritis
NSAIDs: non-steroidal anti inflammatory drugs
PsO: plaque psoriasis
PsA: psoriatic arthritiss
RA: rheumatoid arthritis
RAPID3: routine assessment of patient index data 3
TNF: tumor necrosis factor
UC: ulcerative colitis

**Appendix B:** Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

| Drug Name | Dosing Regimen | Dose Limit/ Maximum Dose |
|---|---|---|
| acitretin (Soriatane®) | **PsO**<br>25 or 50 mg PO QD | 50 mg/day |
| azathioprine (Azasan®, Imuran®) | **RA**<br>1 mg/kg/day PO QD or divided BID<br>**CD***<br>1.5 – 2 mg/kg/day PO | 3 mg/kg/day |
| corticosteroids<br>- Oral: e.g., prednisone, budesonide<br>-Medium to very high potency topical: e.g., desoximetasone 0.05%, fluocinolone acetonide 0.025%, mometasone 0.1% cream, triamcinolone acetonide 0.1%, augmented betamethasone dipropionate 0.05%, clobetasol propionate 0.05% cream, ointment, gel, or solution, halobetasol propionate 0.05% cream, ointment | **CD***<br>Adult:<br>-prednisone 40 mg – 60 mg PO QD for 1 to 2 weeks, then taper daily dose by 5 mg weekly until 20 mg PO QD, and then continue with 2.5 – 5 mg decrements weekly or IV 50 – 100 mg Q6H for 1 week -<br>budesonide (Entocort EC□ ) 6 – 9 mg PO QD<br>Pediatric:<br>-Prednisone 1 to 2 mg/kg/day PO QD<br>**UC**<br>Adult:<br>-Prednisone 40 mg – 60 mg PO QD, then taper dose by 5 to 10 mg/week<br>-budesonide (Uceris□ ) 9 mg PO QD<br>Pediatric:<br>-Prednisone 1 to 2 mg/kg/day PO QD | Various |
| Cuprimine□ (d-penicillamine) | **RA***<br>Initial dose: 125 or 250 mg PO QD<br>Maintenance dose: 500 – 750 mg/day PO QD | 1,500 mg/day |
| cyclosporine (Sandimmune®, Neoral®) | **PsO**<br>2.5 – 4 mg/kg/day PO divided BID | PsO, RA: 4 mg/kg/day |

| | | |
|---|---|---|
| | **RA**<br>2.5 – 4 mg/kg/day PO divided BID | |
| hydroxychloroquine (Plaquenil®) | **RA***<br>Initial dose: 400 – 600 mg/day PO QD<br>Maintenance dose: 200 – 400 mg/day PO QD | 600 mg/day |
| leflunomide (Arava®) | **RA**<br>Initial dose (for low risk hepatotoxicity or myelosuppression): 100 mg PO QD for 3 days<br>Maintenance dose: 20 mg PO QD | 20 mg/day |
| 6-mercaptopurine (Purixan®) | **CD***<br>50 mg PO QD or 0.75 – 1.5 mg/kg/day PO | 1.5 mg/kg/day |
| methotrexate (Trexall®, Otrexup™, Rasuvo®, RediTrex®, Xatmep™, Rheumatrex®) | **CD***<br>15 – 25 mg/week IM or SC<br>**PsO**<br>10 to 25 mg/week IM, SC or PO or 2.5 mg PO Q12 hr for 3 doses/week<br>**RA**<br>7.5 mg/week PO, SC, or IM or 2.5 mg PO Q12 hr for 3 doses/week | 30 mg/week |
| NSAIDs (e.g., indomethacin, ibuprofen, naproxen, celecoxib) | AS, nr-axSpA: Varies | Varies |
| Pentasa® (mesalamine) | **CD**<br>1,000 mg PO QID | 4 g/day |
| Ridaura® (auranofin) | **RA**<br>6 mg PO QD or 3 mg PO BID | 9 mg/day (3 mg TID) |
| sulfasalazine (Azulfidine®) | **RA**<br>Initial dose: 500 mg to 1,000 mg PO QD for the first week. Increase the daily dose by 500 mg each week up to a maintenance dose of 2 g/day.<br>Maintenance dose: 2 g/day PO in divided doses | RA: 3 g/day<br>UC: 4 g/day |

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.
*Off-label

**Appendix C:** Contraindications/Boxed Warnings

Contraindications:

- Doses > 5 mg/kg in patients with moderate-to-severe heart failure
- Known hypersensitivity to inactive components of the product or to any murine proteins

BBW:

- Serious infections
- Malignancy

**Appendix D:** General Information

- Definition of failure of MTX or DMARDs
  - Failure of a trial of conventional DMARDs:
    - Child-bearing age is not considered a contraindication for use of MTX. Each drug has risks in pregnancy. An educated patient and family planning would allow use of MTX in patients who have no intention of immediate pregnancy.
    - Social use of alcohol is not considered a contraindication for use of MTX. MTX may only be contraindicated if patients choose to drink over 14 units of alcohol per week. However, excessive alcohol drinking can lead to worsening of the condition, so patients who are serious about clinical response to therapy should refrain from excessive alcohol consumption.
- Ulcerative Colitis:
  - For Ulcerative Colitis maintenance therapy, failure is defined as having two or more exacerbations requiring steroid therapy
- Ulcerative colitis: there is insufficient evidence to support the off-label weekly dosing of adalimumab for the treatment of moderate-to-severe UC. It is the position of Centene Corporation® that the off-label weekly dosing of adalimumab for the treatment of moderate-to-severe UC is investigational and not medically necessary at this time.
  - The evidence from the post hoc study of the adalimumab pivotal trial suggests further studies are needed to confirm the benefit of weekly adalimumab dosing for the treatment of UC in patients with inadequate or loss of therapeutic response to treatment with adalimumab every other week. No large, randomized or prospective studies have been published to support the efficacy of the higher frequency of dosing, while national and international treatment guidelines also do not strongly support dose escalation of adalimumab for UC. The current market consensus is that weekly dosing of adalimumab is not medically necessary due to lack of evidence to support its benefit
- Nr-axSpA: guideline recommendations are largely extrapolated from evidence in AS.
- Infliximab used in the treatment of unspecified iridocyclitis (anterior uveitis) has primarily been evaluated in case reports and uncontrolled case series. One phase II clinical trial by Suhler and associates (2009) reported the 2-year follow-up data of patients with refractory uveitis treated with intravenous infliximab as part of a prospective clinical trial. Their 1-year data, published in 2005 (Suhler, 2005) reported reasonable initial success, but an unexpectedly high incidence of adverse events. Of

their 23 patients, 7 developed serious adverse events, including 3 thromboses, 1 malignancy, 1 new onset of congestive heart failure, and 2 cases of drug-induced lupus. The American Optometric Association anterior uveitis clinical practice guidelines recommend alternative therapies that include ophthalmic corticosteroids (e.g., prednisolone, dexamethasone, fluoromethalone) and anticholinergics (e.g., atropine, cyclopentolate, homatropine). If the disease has not responded to topical therapy, oral corticosteroids can be considered

- TNF blockers:
    - Etanercept (Enbrel®), adalimumab (Humira®) and its biosimilars, infliximab (Remicade®) and its biosimilars (Avsola™, Renflexis™, Inflectra®), certolizumab pegol (Cimzia®), and golimumab (Simponi®, Simponi Aria®).

**Appendix E:** Immunomodulator Medical Justification

- The following may be considered for medical justification supporting inability to use an immunomodulator for CD:
    - Inability to induce short-term symptomatic remission with a 3-month trial of systemic glucocorticoids
    - High-risk factors for intestinal complications may include:
        - Initial extensive ileal, ileocolonic, or proximal GI involvement
        - Initial extensive perianal/severe rectal disease
        - Fistulizing disease (e.g., perianal, enterocutaneous, and rectovaginal fistulas)
        - Deep ulcerations
        - Penetrating, stricturing or stenosis disease and/or phenotype
        - Intestinal obstruction or abscess
        - For TNF-inhibitors, high risk factors for postoperative recurrence may include:
        - Less than 10 years duration between time of diagnosis and surgery
        - Disease location in the ileum and colon
        - Perianal fistula
        - Prior history of surgical resection
        - Use of corticosteroids prior to surgery

**Appendix F:** Mayo Score

Mayo Score: evaluates ulcerative colitis stage, based on four parameters: stool frequency, rectal bleeding, endoscopic evaluation and Physician's global assessment. Each parameter of the score ranges from zero (normal or inactive disease) to 3 (severe activity) with an overall score of 12.

| Score | Decoding |
|---|---|
| 0-2 | Remission |
| 3-5 | Mild activity |
| 6-10 | Moderate activity |
| >10 | Severe activity |

**Appendix G:** Dose Rounding Guidelines for Weight-Based Doses

**Infliximab for All Indications**

| Weight-based Dose Range | Vial Quantity Recommendation |
|---|---|
| ≤ 104.99 mg | 1 vial of 100 mg/20 mL |
| 105 to 209.99 mg | 2 vial of 100 mg/20 mL |
| 210 to 314.99 mg | 3 vial of 100 mg/20 mL |
| 315 to 419.99 mg | 4 vial of 100 mg/20 mL |
| 420 to 524.99 mg | 5 vial of 100 mg/20 mL |
| 525 to 629.99 mg | 6 vial of 100 mg/20 mL |
| 630 to 734.99 mg | 7 vial of 100 mg/20 mL |
| 735 to 839.99 mg | 8 vial of 100 mg/20 mL |

**Appendix H:** The 2010 ACR Classification Criteria for RA

Add score of categories A through D; a score of ≥ 6 out of 10 is needed for classification of a patient as having definite RA.

| A | Joint involvement | Score |
|---|---|---|
| | 1 large joint | 0 |
| | 2-10 large joints | 1 |
| | 1-3 small joints (with or without involvement of large joints) | 2 |
| | 4-10 small joints (with or without involvement of large joints) | 3 |
| | > 10 joints (at least one small joint) | 5 |

| B | Serology (at least one test result is needed for classification) | Score |
|---|---|---|
| | Negative rheumatoid factor (RF) and negative anti-citrullinated protein antibody (ACPA) | 0 |
| | Low positive RF or low positive ACPA<br>* Low: < 3 x upper limit of normal | 2 |
| | High positive RF or high positive ACPA<br>* High: ≥ 3 x upper limit of normal | 3 |

| C | Acute phase reactants (at least one test result is needed for classification) | Score |
|---|---|---|
| | Normal C-reactive protein (CRP) and normal erythrocyte sedimentation rate (ESR) | 0 |
| | Abnormal CRP or abnormal ESR | 1 |

| D | Duration of symptoms | Score |
|---|---|---|
| | < 6 weeks | 0 |
| | ≥ 6 weeks | 1 |

**Appendix I:** Clinical Disease Activity Index (CDAI) Score

The Clinical Disease Activity Index (CDAI) is a composite index for assessing disease activity in RA. CDAI is based on the simple summation of the count of swollen/tender joint count of 28 joints along with patient and physician global assessment on VAS (0–10 cm) Scale for estimating disease activity. The CDAI score ranges from 0 to 76.

| CDAI Score | Disease state interpretation |
|---|---|
| ≤ 2.8 | Remission |
| > 2.8 to ≤ 10 | Low disease activity |
| > 10 to ≤ 22 | Moderate disease activity |
| > 22 | High disease activity |

**Appendix J:** Routine Assessment of Patient Index Data 3 (RAPID3) Score

The Routine Assessment of Patient Index Data 3 (RAPID3) is a pooled index of the three patient-reported ACR core data set measures: function, pain, and patient global estimate of status. Each of the individual measures is scored 0 – 10, and the maximum achievable score is 30.

| RAPID3 Score | Disease state interpretation |
|---|---|
| ≤ 3 | Remission |
| 3.1 to 6 | Low disease activity |
| 6.1 to 12 | Moderate disease activity |
| > 12 | High disease activity |

**V. Dosage and Administration**

| Drug Name | Indication | Dosing Regimen | Maximum Dose |
|---|---|---|---|
| Infliximab (Avsola, Inflectra, Remicade, Renflexis)* *Also see Appendix G: Dose Rounding Guidelines for Weight-Based Doses | CD, UC | Initial dose:<br>Adults/Pediatrics: 5 mg/kg IV at weeks 0, 2 and 6<br>Maintenance dose:<br>Adults/Pediatrics: 5 mg/kg IV every 8 weeks.<br>For CD: Some adult patients who initially respond to treatment may benefit from increasing the dose to 10 mg/kg if they later lose their response | CD, Adults: 10 mg/kg every 8 weeks<br>UC, Adults: 5 mg/kg every 8 weeks Pediatrics: 5 mg/kg every 8 weeks |
| | PsA PsO | Initial dose: 5 mg/kg IV at weeks 0, 2 and 6<br>Maintenance dose: 5 mg/kg IV every 8 weeks | 5 mg/kg every 8 weeks |
| | RA | In conjunction with MTX<br>Initial dose: 3 mg/kg IV at weeks 0, 2 and 6 | 10 mg/kg every 4 weeks |

| | | | |
|---|---|---|---|
| | | Maintenance dose: 3 mg/kg IV every 8 weeks<br>Some patients may benefit from increasing the dose up to 10 mg/kg or treating as often as every 4 weeks | |
| | AS | Initial dose: 5 mg/kg IV at weeks 0, 2 and 6<br>Maintenance dose: 5 mg/kg IV every 6 weeks | 5 mg/kg every 6 weeks |
| | Kawasaki disease (off-label) | single infusion of 5 mg/kg given over 2 hours | 5 mg/kg |

**VI. Product Availability**

| Drug Name | Availability |
|---|---|
| Infliximab-axxq (Avsola) | Single-use vial: 100 mg/20 mL |
| Infliximab-dyyb (Inflectra) | Single-use vial: 100 mg/20 mL |
| Infliximab (Remicade) | Single-use vial: 100 mg/20 mL |
| Infliximab-abda (Renflexis) | Single-use vial: 100 mg/20 Ml |

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**Coding Implications**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J1745 | Injection, infliximab, excludes biosimilar, 10 mg |
| Q5103 | Injection, infliximab-dyyb, biosimilar, (inflectra), 10 mg |
| Q5104 | Injection, infliximab-abda, biosimilar, (renflexis), 10 mg |
| Q5121 | Injection, infliximab-axxq, biosimilar, (avsole), 10mg |

**Revision Log**

| Reviews, Revisions, and Approvals | Revision Date | Approval Date |
|---|---|---|
| Policy Created | | 05.24 |
| 2Q 2024: for axial spondyloarthritis and psoriatic arthritis, added that maximum dose escalation allowed per prescriber information with documentation of inadequate response; removed contraindication from appendix C; reviewed and updated references. | 05.24 | 06.24 |

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed healthcare professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program

approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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