This Policy applies to all SECUR affiliates, associates, and subsidiaries.

Approved by Courtney Gonzales, Director of Health Services on behalf of the Utilization Management Committee.

PURPOSE

This coverage determination guideline serves to address infliximab, a chimeric monoclonal antibody that binds specifically to tumor necrosis for factor alpha (TNFa) and blocks its activity. Overproduction of TNFa, which is a key inflammatory mediator, leads to inflammation in conditions such as Chron's disease, rheumatoid arthritis, and other autoimmune diseases.

For SECUR Health Plan members, National Coverage Determinations (NCD) and Local Coverage Determinations (LCD) will be applied to requests when applicable. SECUR Health Plan Coverage Determination Guidelines (CDG) will be utilized in the absence of an appropriate NCD and/or LCD.

DEFINITIONS

None

POLICY

SECUR Health Plan considers infliximab medically necessary in the following:

1. To reduce the signs and symptoms and induce and maintain clinical remission in members with moderately to severely active Chron's disease who have experienced inadequate response to conventional therapy such as corticosteroids, aminosalicylates, and immunosuppressive agents.

2. To reduce the number of draining enterocutaneous and rectovaginal fistulas and maintaining closure of the fistula(s) for members with fistulizing Chron's disease. Normal treatment is indicated at week 0, 2, and 6. Subsequent treatments will be considered medically necessary if the member responds to the initial treatment as demonstrated by a reduction in signs and symptoms.

3. To reduce the signs and symptoms of active arthritis to inhibit the progression of structural damage and improve physical function in members with psoriatic arthritis. Normal treatment is indicated at week 0, 2, and 6. Subsequent treatments will be considered medically necessary if the member responds to the initial treatment as demonstrated by a reduction in signs and symptoms.

4. When used in combination with methotrexate to reduce the signs and symptoms to inhibit the progression of structural damage and improve physical function in members with moderate to severely active rheumatoid arthritis. Normal treatment is indicated at week 0, 2, and 6, and then approximately once every

8 weeks.

5. To reduce the signs and symptoms in members with active ankylosing spondylitis. Normal treatment is indicated at weeks 0, 2, and 6. Subsequent treatment will be considered medically necessary if the member shows a positive response to initial treatment as indicated by a reduction in signs and symptoms.

6. Treatment of members with chronic severe plaque psoriasis, defined as plaques covering at least 10% of the body surface, who have failed prior treatment with psoralen-ultraviolet A (UVA) or ultraviolet B (UVB) light therapy, or are candidates for systemic therapy when other conventional treatments have failed, or the member has contraindications to these treatments. Close monitoring and frequent follow up visits with the ordering practitioner are needed in these instances. Normal treatment is indicated at weeks 0, 2, and 6, and every 8 weeks thereafter.

7. To reduce signs and symptoms, achieve clinical remission and mucosal healing, and eliminate corticosteroid use in members with moderate to severe active ulcerative colitis who have had an inadequate response to conventional treatment such as aminosalicylates, corticosteroids, or immunosuppressants, unless the member is unable to tolerate those drugs. Normal treatment is indicated at weeks 0, 2, and 6, and every 8 weeks thereafter.

8. Off-label use for hidradenitis suppurativa in the treatment of members with severe disease refractory to systemic antibiotics and surgical treatments.

9. Off-label use for Behcet's Disease (BD), also known as Behcet's Syndrome, in members without adequate response to initial therapy, for the treatment of clinical manifestations of BD such as severe ocular involvement, major organ involvement, severe gastrointestinal or neurological involvement, and resistant cases of joint or mucocutaneous involvement such as painful oral and/or genital ulcers.

10. Off-label use for members with chronic pulmonary sarcoidosis who remain symptomatic despite treatment for three (3) or more months with steroids at 10 mg/day or greater and immunosuppressants or have a contraindication or intolerance to one immunosuppressant and the member is not receiving infliximab in conjunction with either of the following:

    - Biologic disease modifying antirheumatic drugs such as etanercept, adalimumab, certolizumab, or golimumab
    - Janus kinase inhibitor (tofacitinib)

    The US Food and Drug Administration have not yet approved the current and prospective roles of infliximab in the treatment of pulmonary sarcoidosis and it is recommended that providers consult the literature for proper dosing in these members.

For members unable to tolerate methotrexate or in the rare instance that methotrexate is contraindicated, treatment with infliximab alone will be covered provided that supporting documentation clearly indicates the reason the member is not able to take methotrexate.

For the above, SECUR Health Plan will only consider the use of infliximab medically necessary when no contraindications to its use exist including Class III or IV congestive heart failure and/or untreated active or latent

tuberculosis.

When used in combination with another biologic such as etanercept, anakinra, adalimumab, certolizumab, golimumab, or tofacitinib, infliximab is considered not medically necessary.

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