Blue Cross Blue Shield Blue Care Network of Michigan

Nonprofit corporations and independent licensees of the Blue Cross and Blue Shield Association

Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

Effective Date: 10/03/2024

Cimzia® (certolizumab pegol)

HCPCS: J0717

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Coverage of the requested drug is provided when all the following are met:
   a. FDA approved age.
   b. Diagnosis of rheumatoid arthritis (RA)
      i. Trial and failure of at least 3 months of one disease-modifying anti-rheumatic agent (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine
   c. Diagnosis of psoriatic arthritis (PsA)
   d. Diagnosis of ankylosing spondylitis (AS)
   e. Diagnosis of Crohn's disease (CD)
      i. Treatment with an adequate course of conventional therapy (such as steroids for 7 days, immunomodulators such as azathioprine for at least 2 months) has been ineffective or is contraindicated or not tolerated
   f. Diagnosis of psoriasis (PsO)
      i. Trial and failure, contraindication, or intolerance to one topical corticosteroid
   g. Diagnosis of Non-Radiographic Axial Spondyloarthritis (NRAS)
   h. Not to be used in combination with other biologics or targeted DMARDs for the same indication
   i. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN utilization management medical drug list and/or as listed in BCBSM/BCN's prior authorization and step therapy documents
   j. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in BCBSM/BCN utilization management medical drug list and/or as listed in BCBSM/BCN's prior authorization and step therapy documents

B. Quantity Limitations, Authorization Period and Renewal Criteria
   a. Quantity Limits: Align with FDA recommended dosing
   b. Authorization Period: One year at a time
   c. Renewal Criteria: Clinical documentation must be provided to confirm that current criteria are met and that the medication is providing clinical benefit

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at http://www.cms.hhs.gov/. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

Background Information:

- Cimzia is an anti-tumor necrosis factor (TNF) agent indicated for:
    - Adults with moderately to severely active rheumatoid arthritis
    - Adults with active psoriatic arthritis
    - Adults with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy
    - Adults with active ankylosing spondylitis
    - Adults with active non-radiographic axial spondyloarthritis
    - Adults with moderate-to-severe psoriasis who are candidates for systemic therapy or phototherapy
    - Patients 2 years of age and older with active polyarticular juvenile idiopathic arthritis
- Rheumatoid Arthritis (RA)
    - The 2021 American College of Rheumatology (ACR) Guidelines for the Treatment of Rheumatoid Arthritis (RA) established recommendations for the care of adult RA patients. The guidelines state that treatment decisions should follow a shared decision-making process and should be reevaluated within a minimum of 3 months based on the efficacy and tolerability of the DMARD(s) chosen.
    - For the initial treatment of symptomatic RA, the guidelines strongly recommend the use of conventional synthetic disease-modifying antirheumatic drug (csDMARD) monotherapy in those who are DMARD-naive. csDMARD monotherapy is a less costly first line treatment option with an extensive safety record accompanied by well-documented clinical efficacy and a large body of clinical experience and familiarity among prescribers. csDMARDs in the guidelines refer to methotrexate (MTX), hydroxychloroquine, leflunomide (LEF), and sulfasalazine. Azathioprine, cyclosporine, minocycline, and gold were not included due to their infrequent use in RA and lack of new data since the prior guidelines were published. Oral MTX is recommended as the preferred initial DMARD for patients with moderate-to-high disease activity, and hydroxychloroquine is recommended as the preferred initial DMARD for patients with low disease activity.
    - If disease activity remains moderate or high despite optimal dosing of methotrexate monotherapy, the use of dual therapy with methotrexate plus biologic DMARD (bDMARD; etanercept, adalimumab, infliximab, golimumab, certolizumab pegol, abatacept, tocilizumab, sarilumab, rituximab) or targeted synthetic DMARD (tsDMARD; tofacitinib, baricitinib, upadacitinib) therapy is conditionally recommended over the use of triple therapy (i.e., addition of sulfasalazine and hydroxychloroquine). The guidelines do not inform preference of bDMARD over tsDMARD therapy (or vice-versa) for use in combination with MTX. No one agent has been shown to be superior to another. The guidelines do acknowledge the emergence of safety signals for the JAK inhibitor class (tsDMARD), and state that further modification of this recommendation may be necessary as additional data are published.

- A treat-to-target approach is conditionally recommended over usual care for patients who have had an inadequate response to bDMARDs or tsDMARDs. Treat-to-target refers to a systematic approach involving frequent monitoring of disease activity using validated instruments and modification of treatment to minimize disease activity with the goal of reaching a pre-defined target (low disease activity or remission).

- Psoriatic Arthritis (PsA)

  - Psoriatic Arthritis (PsA) is a chronic inflammatory disease often associated with psoriasis. Psoriasis is an autoimmune disease affecting the skin, resulting in scaly red and white patches. These patches, called plaques, may appear anywhere on the body. The inflammation may also develop in the joints, which is classified as PsA. PsA occurs in up to 30% of patients with psoriasis, most commonly appearing between the ages of 30 and 50. PsA causes pain, stiffness, and swelling in and around the joints. If not properly treated, progressive joint damage may occur.

  - Per the 2018 American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF) guideline for the treatment of psoriatic arthritis:

    - All recommendations for treatment-naive patients with active PsA are conditional based on low- to very-low quality evidence.

    - In treatment-naïve patients, oral systemic medications (OSMs), such as methotrexate, sulfasalazine, cyclosporine, and leflunomide, may be used in patients without severe psoriatic arthritis and without severe psoriasis. OSMs have robust longitudinal safety and efficacy data in patients with PsA. Maximal response to OSMs are most commonly achieved within 3 months of therapy.

    - If PsA remains active despite OSM therapy, switching to a TNFi, an interleukin 17 inhibitor (IL-17i), or an interleukin 12/23 inhibitor (IL-12/23i) is recommended over switching to a different OSM; switching to a TNFi biologic over an IL-17i or IL-12/23i biologic is conditionally recommended in this scenario based on moderate quality evidence. Additional treatment options include Orencia® (abatacept) and Xeljanz® (tofacitinib). The detailed recommendations for subsequent therapies can be found in the 2018 ACR/NPF guideline for the treatment of psoriatic arthritis.

- Ankylosing Spondylitis (AS)

  - Axial spondyloarthritis, comprising ankylosing apondylitis (AS) and non-radiographic axial spondyloarthritis (NRAS), is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

  - The 2019 American College of Rheumatology recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with nonsteroidal anti-inflammatory drugs (NSAIDS), treatment with TNFi are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx® (secukinumab) or Taltz® (ixekizumab) is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.

- Crohn's disease (CD)

  - The 2018 American College of Gastroenterology (ACG) guidelines establish therapeutic recommendations for patients with Crohn's disease based upon disease location, disease severity, disease-associated complications, and future disease prognosis. Therapeutic approaches are individualized according to the symptomatic response and tolerance to medical intervention. Current therapeutic approaches should be considered a sequential continuum to treat acute disease or induce clinical remission and then to maintain response/remission. In general, clinical evidence of improvement should be evident within 2 – 4 weeks and the maximal improvement should occur within 12 – 16 weeks. Those with continued symptoms should be treated with an alternative therapy for mild to moderate disease, have their medication dose adjusted in order to attempt to optimize therapy, or advance to treatment for moderate to severe disease according to their clinical status.

  - Corticosteroids are used primarily for the treatment of flares of CD. Conventional corticosteroids are effective for reducing the signs and symptoms of active CD and induction of remission in patients with moderately to severely active CD. Oral corticosteroids are effective and can be used for short-term use in alleviating signs and symptoms of moderate to severely active disease. The ACG guidelines recommend prednisone equivalent doses ranging from 40 to 60 mg per day. These doses are typically maintained for 1 –2 weeks and tapered at 5 mg weekly until 20 mg and then 2.5 –5 mg weekly. Once begun, care should be taken to ensure that corticosteroids are successfully discontinued, and steroid-sparing agents should be used.

  - In patients with moderate-to-severe CD who remain symptomatic despite current or prior corticosteroid therapy, mercaptopurine, azathioprine, and intramuscular or subcutaneous methotrexate are effective as steroid-sparing agents and are recommended by the guidelines. Maximum effectiveness of these agents can be seen between 8 to 12 weeks from therapy initiation. Methotrexate is also recommended in combination with steroids as effective for treatment of moderately active steroid-dependent/resistant CD. Cyclosporine, tacrolimus, and mycophenolate are not recommended for treatment of CD.

  - Biologics, such as TNFi are recommended to treat CD that is resistant to treatment with corticosteroids, thiopurines, or methotrexate. The ACG guidelines also recommend the use of biologics in combination with immunosuppressants to help decrease the formation of antibodies against the biologic therapy. There are no robust, published studies to support use of biologic agents in combination.

  - The 2021 American Gastroenterological Association (AGA) guidelines include similar recommendations for the management of moderate-to-severe CD compared to the recommendations cited in the 2018 ACG guidelines. Both guidelines recommend corticosteroids over no treatment for induction of remission. Additionally, both guidelines recommend thiopurines, such as azathioprine or 6-mercaptopurine, as steroid-sparing agents for maintenance of remission. The AGA guidelines also recommend the same biologic agents cited in the ACG guidelines for treatment of CD, with the exception of Tysabri® (natalizumab), which the AGA suggests against use of due to its associated risk of progressive multifocal leukoencephalopathy (PML).

  - Of note, the AGA guidelines conditionally recommend earlier introduction of biologic therapy prior to failure of corticosteroids; however, this recommendation is supported by a low level of clincial evidence. To date, no blinded randomized controlled trials (RCTs) have demonstrated the superiority of early introduction of biologic therapy compared to conventional induction therapy with corticosteroids followed by steroid-sparing therapy. The 2021 AGA guideline authors also acknowledge that earlier therapy with either combination immunomodulotor plus biologic therapy or biologic monotherapy may result in over-treating some patients and potentially exposing them to treatment-related risks and costs with limited benefit.

- Psoriasis (PsO)

    - Psoriasis is a chronic, painful and life-altering immune-mediated disease which predominantly manifests with skin and joint involvement. Patients may also experience significant cardiovascular and psychological comorbidities. Approximately 2% of U.S. adults are affected by psoriasis (men and women equally), and it can occur at any age. Approximately 90% of psoriasis-affected patients have plaque psoriasis, which is characterized by well-defined round or oval plaques that vary in size and often coalesce. The severity of psoriasis is defined as: mild = less than 3% of body affected; moderate = 3-10% of body affected; and severe being more than 10% of the body affected.

    - Per the 2020 Joint American Academy of Dermatology - National Psoriasis Foundation (AAD-NPF) guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures: topical corticosteroids provide a high efficacy and good safety option for patients with localized disease. They are generally recommended as first-line therapy. Choice of steroid potency may depend on severity, location, patient preference, and patient age, while the duration of treatment may vary with steroid potency, location and severity of disease often ranging from 2-12 weeks. Therapeutic regimens may include 2-4 weeks with a topical steroid applied twice daily, followed by a maintenance regimen where topical steroids are alternated with a steroid-sparing topical agent. Treatment with topical steroids for over 12 weeks is recommended under careful supervision by a physician.

    - Per the 2019 AAD-NPF guidelines of care for the management and treatment of psoriasis with phototherapy: phototherapy serves as a reasonable and effective treatment option for patients requiring more than topical medications and/or those wishing to avoid systemic medications or simply seeking an adjunct to a failing regimen. Guidelines also state that the majority of patients with mild-to-moderate disease have adequate disease control with topical therapies and phototherapy alone.

    - Per the 2020 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with systemic nonbiologic therapies: many oral medications, including methotrexate, cyclosporine, and acitretin, have been used for decades to treat psoriasis, each with its own benefits and risks. Most work by targeting the immune system, whereas others, such as acitretin, work predominantly by decreasing keratinocyte hyperproliferation, thus restoring the normal epidermal differentiation. Both methotrexate and cyclosporine are category A guideline recommendations for the treatment of moderate to severe psoriasis in adults and for severe, recalcitrant psoriasis, respectively. Studies examining the use of methotrexate and cyclosporine in psoriasis showed the primary efficacy endpoints met within 12-16 weeks. Acitretin is a category B guideline recommendation as monotherapy for plaque psoriasis, with full treatment response expected within 3-6 months.

    - Per the 2019 Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with biologics: biologic agents, as monotherapy or combined with other topical or systemic medications, have a high benefit-to-risk ration. TNFi and IL-12/IL-23i, IL-23i, and IL-17i biologics have a category "A" recommendation as a monotherapy treatment option for adult patients with moderate-to-severe plaque psoriasis. Guidelines do not recommend one product over another and note the similar efficacy seen across biologics within the same class. There are no published, robust studies to support the use of more than one biologic product in combination.

- Non-Radiographic Axial Spondyloarthritis (NRAS)

    - Axial spondyloarthritis, comprising ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (NRAS), is the main form of chronic inflammatory arthritis affecting the axial skeleton. Non-radiographic means that damage to the joints is not visible on X-ray. When changes to the vertebrae (the bones of the

spine) or sacroiliac joints don't show any changes on an X-ray, that's known as NRAS. Once the joints are clearly affected on an X-ray, a person can be diagnosed with AS.

- The 2019 American College of Rheumatology recommendations for AS and NRAS are similar. In adult patients who have active disease despite treatment with nonsteroidal anti-inflammatory drugs (NSAIDS), treatment with TNFi are recommended. They do not recommend any particular TNFi as the preferred choice for the typical patient. Cosentyx (secukinumab) or Taltz is recommended over the use of a second TNFi in patients with primary nonresponse to the first TNFi, whereas for patients with a secondary nonresponse (i.e. those who relapse after an initial response) it may be beneficial to switch to a different TNFi rather than immediately switch to a different biologic class. In the case of nonresponse (primary or secondary), the guidelines recommend against switching to treatment with a biosimilar since clinical response would not be expected to be different.

- Polyarticular Juvenile Idiopathic Arthritis (pJIA)

  - Juvenile idiopathic arthritis (JIA) defines a collection of inflammatory arthritides of unknown etiology. JIA onset is prior to 16 years of age with a minimum duration of 6 weeks and other potential causes of synovitis are excluded. JIA can be subdivided into pJIA and systemic JIA.

  - pJIA is defined by the presence of more than 4 affected joints in the first 6 months of illness and comprises 20-30% of children with JIA. Therapy is directed toward treating the underlying inflammation and preventing JIA-associated complications and adverse effects of its treatment.

  - The 2019 American College of Rheumatology/Arthritis Foundation (ACR/AF) guideline for the treatment of JIA strongly recommends initial therapy for pJIA with a DMARD such as MTX or LEF. MTX is conditionally recommended over LEF as it has a greater volume of data supporting its effectiveness compared to LEF and can be administered subcutaneously (recommended) or orally. The guidelines consider an adequate trial of a DMARD to be 3 months.

  - If moderate or high disease activity persists despite adequate DMARD use, the ACR/AF guidelines recommend biologic agents either in combination with a DMARD or as monotherapy in certain situations. Biologic agents FDA approved for pJIA in patients 2 years of age and older include Humira® (adalimumab), Enbrel® (etanercept), tocilizumab, Orencia® (abatacept), Simponi Aria® (golimumab), Xeljanz® (tofacitinib), Xeljanz (tofacitinib) oral solution, and Cimzia (certolizumab pegol).

  - Of note, biologic therapy may be an appropriate initial therapy in pJIA patients with risk factors and involvement of high-risk joints, high disease activity, and/or for those judged to be at high risk of disabling joint damage.

  - There is the most experience with tumor necrosis factor inhibitors (TNFi; Humira, Enbrel, Simponi Aria) as initial biologic therapy; however, the preferred class of initial biologic is not specified in the guideline recommendations due to a lack of comparative data and the consideration that non-TNFi biologics may be preferred in certain patient-specific scenarios. If a TNFi is started as the initial biologic, switching to a non-TNFi (tocilizumab or Orencia) is recommended over switching to a second TNFi. An exception to this is for those who had a good initial response to the first TNFi.

References:

1. Cimzia [prescribing information]. Smyrna, GA: UCB, Inc. September 2019.
2. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.
3. Fraenkel L, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Care & Research. 2021 Jul; 73 (7):924-939.
4. Singh JA, Guyatt G, Ogdie A, et al. 2018 American College of Rheumatology/National Psoriasis Foundation Guideline for the Treatment of Psoriatic Arthritis. Arthritis & Rheumatology. 2018; 0(0): 1-28. https://www.rheumatology.org/Portals/0/Files/PsA-Guideline-Early-View-Version.pdf.
5. Lichtenstein GR, Loftus EV, Isaacs KL, et al. ACG clinical guideline: management of crohn's disease in adults. AJG. 2018 April; 113 (4): 481-517.
6. Feuerstein JD, Ho EY, Shmidt E, et al. AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease. Gastroenterology. 2021;160(7):2496-2508. doi:10.1053/j.gastro.2021.04.022
7. Elmets CA, Lim HW, Stoff B, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis with phototherapy [published correction appears in J Am Acad Dermatol. 2020 Mar;82(3):780]. J Am Acad Dermatol. 2019;81(3):775-804. doi:10.1016/j.jaad.2019.04.042
8. Elmets CA, Korman NJ, Prater EF, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures [published online ahead of print, 2020 Jul 30]. J Am Acad Dermatol. 2020;S0190-9622(20)32288-X. doi:10.1016/j.jaad.2020.07.087
9. Menter A, Gelfand JM, Connor C, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management of psoriasis with systemic nonbiologic therapies. J Am Acad Dermatol. 2020;82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044
10. Menter A, Strober BE, Kaplan DH, et al. Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with biologics. J Am Acad Dermatol. 2019;80(4):1029-1072. doi:10.1016/j.jaad.2018.11.057
11. Ward, MM, Deodhar, A, Akl, EA, et al. 2019 Update of the American College of Rheumatology/
12. Spondylitis Association of America/Spondyloarthritis Research and Treatment Network Recommendations for the Treatment of Ankylosing Spondylitis and Nonradiographic Axial Spondyloarthritis. Arthritis Rheumatol. 2019 Oct;71(10):1599-1613.

<table>
<tr><th colspan="3">Policy History</th></tr>
<tr><th>#</th><th>Date</th><th>Change Description</th></tr>
<tr><td>2.8</td><td>Effective Date: 10/03/2024</td><td>Added “for the same indication” to the not to be used in combination with other biologics or targeted DMARDs criteria</td></tr>
<tr><td>2.7</td><td>Effective Date: 12/14/2023</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.6</td><td>Effective Date: 12/01/2022</td><td>Annual review of criteria was performed, no changes were made</td></tr>
<tr><td>2.5</td><td>Effective Date: 12/09/2021</td><td>Updated to remove FDA approved indications, the phototherapy and oral DMARD criteria for psoriasis, the oral DMARD criteria for psoriatic arthritis, and added criteria requiring trial of one topical corticosteroid for psoriasis</td></tr>
<tr><td>2.4</td><td>Effective Date: 02/04/2021</td><td>Removal of the topical steroid criteria for psoriasis indication</td></tr>
<tr><td>2.3</td><td>Effective Date: 12/03/2020</td><td>Criteria updated to align management between pharmacy and medical benefit for all listed indications. Updated all background information</td></tr>
<tr><td>2.2</td><td>Effective Date: 06/11/2020</td><td>Annual review of medical policy</td></tr>
<tr><td>2.1</td><td>Effective Date: 11/01/2018</td><td>Updated to add required prescribers per indication</td></tr>
<tr><td>2.0</td><td>Effective Date: 08/09/2018</td><td>Annual Review of Medical Policy</td></tr>
<tr><td>1.9</td><td>Effective Date: 08/10/2017</td><td>Take off steps for medical only</td></tr>
<tr><td>1.8</td><td>Effective Date: 07/05/2017</td><td>UM medical management system update for MAPPO and BCNA
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>Yes</td></tr>
<tr><td>BCNA</td><td>Yes</td></tr>
</table></td></tr>
<tr><td>1.7</td><td>Effective Date: 07/01/2017</td><td>UM medical management system update for BCN
<table>
<tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr>
<tr><td>BCBS</td><td>Yes</td></tr>
<tr><td>BCN</td><td>Yes</td></tr>
<tr><td>MAPPO</td><td>No</td></tr>
<tr><td>BCNA</td><td>No</td></tr>
</table></td></tr>
<tr><td>1.6</td><td>Effective Date: 03/23/2017</td><td>Update to remove pharmacy benefit references</td></tr>
<tr><td>1.5</td><td>Effective Date: 02/09/2017</td><td>Annual review and template update</td></tr>
<tr><td>1.4</td><td>Effective Date: 01/01/2016</td><td>Document updated with specified drugs required</td></tr>
</table>

<table>
<tr><td>1.3</td><td>Effective Date:
04/01/2015</td><td>UM medical management system update for BCBS
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table></td></tr>
<tr><td>1.2</td><td>Effective Date:
02/12/2015</td><td>Criteria Update:
Updated requirement with specific number of tried and failed biologics from at least one and at least two for Crohn's Disease and other diagnoses respectively to non-specified number of agents tried.</td></tr>
<tr><td>1.1</td><td>Effective Date:
02/16/2013</td><td>Criteria Update</td></tr>
<tr><td>1.0</td><td>Effective Date:
04/22/2010</td><td>New Policy</td></tr>
</table>

** The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or http://dailymed.nlm.nih.gov/dailymed/index.cfm.*