Wellmark Advantage Health Plan

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Effective Date: 01/01/2022

Orencia® (abatacept)

HCPCS: J0129

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 a 3-month trial of one disease-modifying anti-rheumatic drug (DMARD) unless contraindicated or not tolerated. Examples include: methotrexate, hydroxychloroquine, leflunomide, sulfasalazine
   c. Diagnosis of juvenile idiopathic arthritis (JIA)
      i. Trial and failure of at least a 3-month trial of one DMARD unless contraindicated or not tolerated. Examples include: methotrexate and leflunomide
   d. Diagnosis of psoriatic arthritis (PsA)
   e. Not to be used in combination with other biologics or targeted DMARDs
   f. Trial and failure, contraindication, OR intolerance to the preferred drugs as listed in Wellmark Advantage Health Plan's utilization management medical drug list and/or 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 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:

- Orencia is a biologic disease-modifying agent that functions as a selective T-cell costimulation blocker. It is approved to treat rheumatoid arthritis, juvenile idiopathic arthritis (JIA), and psoriatic arthritis as monotherapy or concomitantly with disease-modifying antirheumatic drugs (DMARDs). Concomitant use with other potent immunosuppressants (including other biologics and targeted DMARDs like Janus kinase (JAK) inhibitors), however, is not recommended.

- Orencia may be administered as a subcutaneous injection or an intravenous (IV) infusion for any of the approved indications. Of note, subcutaneous Orencia is indicated for children 2 years of age and older with JIA, whereas administration of Orencia as an IV infusion should only be used in children 6 years of age and older with JIA. Refer to the prescribing information for additional details.

- Rheumatoid Arthritis

    - 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 DMARD (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).

- Juvenile Idiopathic Arthritis

    - Juvenile idiopathic arthritis (JIA) defines a collection of inflammatory arthritides of unknown etiology. 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 polyarticular JIA and systemic JIA.
    - Polyarticular 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 disease-modifying anti-rheumatic agent (DMARD) such as methotrexate (MTX) or leflunomide. MTX is conditionally recommended over leflunomide as it has a greater volume of data supporting its effectiveness compared to leflunomide 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 an adequate DMARD trial, 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), Actemra® (tocilizumab), Orencia® (abatacept), Simponi Aria® (golimumab), Xeljanz® (tofacitinib), and Xeljanz (tofacitinib) oral solution.

- 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

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- 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 abatacept) 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.

- Psoriatic Arthritis

    - 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. Tumor necrosis factor inhibitor (TNFi) biologics are recommended in cases of severe PsA and severe PsO; however, OSMs may be a suitable option for those who prefer an oral drug over an injectable, or those with contraindications to TNFi treatment including congestive heart failure, previous serious infections, recurrent infections, or demyelinating disease. 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 IL-17i, or an IL-12/23i biologic 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.

References:

1. Ringold et al. 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Treatment of JIA. Arthritis Care and Research. Vol 71 No 6 Jun 2019.
2. 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
3. Singh JA, et al. 2015 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. Arthritis Rheumatol. 2016 Jan; 68(1): 1-26.
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5. Cimzia (certolizumab pegol) [prescribing information]. Smyrna, GA: UCB, Inc. September 2019.
6. Cosentyx (secukinumab) [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals; June 2020.
7. Enbrel (etanercept) [prescribing information]. Thousand Oaks, CA: Immunex Corporation; March 2020.
8. Humira (adalimumab) [prescribing information]. North Chicago, IL: AbbVie; March 2020.
9. Inflectra (infliximab-dyyb) [prescribing information].New York, NY: Pfizer; June 2019.
10. Kevzara (sarilumab) [prescribing information]. Bridgewater, NJ: Sanofi0Aventis; April 2018.
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13. Orencia (abatacept) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; June 2020.
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15. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; May 2020.
16. Renflexis (infliximab-abda) [prescribing information]. Whitehouse Station, NJ: Merc Sharp & Dohme Corp; February 2020.
17. Rinvoq (upadacitinib) [prescribing information]. North Chicago, IL: AbbVie Inc; July 2020.
18. Rituxan (rituximab) [prescribing information]. South San Francisco, CA: Genentech Inc; August 2020.
19. Simponi (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.
20. Simponi Aria (golimumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; September 2019.
21. Stelara (ustekinumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; July 2020.
22. Taltz (ixekizumab) [prescribing information]. Indianapolis, IN: Eli Lilly and Co; May 2020.
23. Tremfya (guselkumab) [prescribing information]. Horsham, PA: Janssen Biotech Inc; July 2020.
24. Xeljanz (tofacitinib) [prescribing information]. New York, NY: Pfizer; December 2019.

Policy History		
#	Date	Change Description
1.0	Effective Date: 12/09/2021	Effective date of policy

** 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.*