# Orencia (abatacept) IV

Policy Number: MC/PC 031
Effective Date: May 1, 2025

Instructions for Use

**Table of Contents** **Page**



**Related Policies**

- N/A

## Coverage Rationale

**This policy is applicable for Orencia (abatacept) for injection for intravenous infusion only.**

### Polyarticular Juvenile Idiopathic Arthritis (PJIA)

For initial coverage of Orencia (abatacept) for Polyarticular Juvenile Idiopathic Arthritis (PJIA), the following will be required:

- All of the following:
  - Diagnosis of moderately to severely active polyarticular juvenile idiopathic arthritis **and**
  - Prescribed by or in consultation with a rheumatologist **and**
  - Minimum duration of a 6-week trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:
    - leflunomide
    - methotrexate

  **OR**
- For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

For reauthorization coverage of Orencia (abatacept) for Polyarticular Juvenile Idiopathic Arthritis (PJIA), the following will be required:

- Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:
  - Reduction in the total active (swollen and tender) joint count from baseline
  - Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

### Prophylaxis for Acute Graft versus Host Disease (aGVHD)

For initial coverage of Orencia (abatacept) Prophylaxis for Acute Graft versus Host Disease (aGVHD), the following will be required:

- Used for prophylaxis of acute graft versus host disease (aGVHD) and
- Patient is 2 years of age or older and

- Patient will receive hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor and
- Recommended antiviral prophylactic treatment for Epstein-Barr Virus (EBV) reactivation (e.g., acyclovir) will be administered prior to Orencia and continued for six months after HSCT and
- Used in combination with both of the following:
    - calcineurin inhibitor (e.g., cyclosporine, tacrolimus)
    - methotrexate

### Psoriatic Arthritis (PsA)

For initial coverage of Orencia (abatacept) for Psoriatic Arthritis (PsA), the following will be required:

- All of the following:
    - Diagnosis of active psoriatic arthritis (PsA) **and**
    - One of the following:
        - Actively inflamed joints
        - Dactylitis
        - Enthesitis
        - Axial disease
        - Active skin and/or nail involvement **and**
    - Prescribed by or in consultation with one of the following:
        - Dermatologist
        - Rheumatologist

  **OR**
- For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

For reauthorization coverage of Orencia (abatacept) for Psoriatic Arthritis (PsA), the following will be required:

- Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:
    - Reduction in the total active (swollen and tender) joint count from baseline
    - Improvement in symptoms (e.g., pain, stiffness, pruritus, inflammation) from baseline
    - Reduction in the body surface area (BSA) involvement from baseline

### Rheumatoid Arthritis (RA)

For initial coverage of Orencia (abatacept) for Rheumatoid Arthritis (RA), the following will be required:

- All of the following:
    - Diagnosis of moderately to severely active rheumatoid arthritis **and**
    - Prescribed by or in consultation with a rheumatologist **and**
    - Minimum duration of a 3-month trial and failure, contraindication, or intolerance to one of the following conventional therapies at maximally tolerated doses:
        - methotrexate
        - leflunomide
        - sulfasalazine

  **OR**
- For continuation of prior Orencia therapy, defined as no more than a 45-day gap in therapy

For reauthorization coverage of Orencia (abatacept) for Rheumatoid Arthritis (RA), the following will be required:

- Patient demonstrates positive clinical response to therapy as evidenced by at least one of the following:
    - Reduction in the total active (swollen and tender) joint count from baseline
    - Improvement in symptoms (e.g., pain, stiffness, inflammation) from baseline

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

| HCPCS Code | Description |
|---|---|
| J0129 | Injection, abatacept, 10 mg |

| ICD-10 Code | Description |
|---|---|
| D89.810 | Acute graft-versus-host disease |
| M05.10–M05.19 | Rheumatoid lung disease with rheumatoid arthritis of unspecified site |
| M05.20–M05.29 | Rheumatoid vasculitis with rheumatoid arthritis |
| M05.30–M05.39 | Rheumatoid heart disease with rheumatoid arthritis |
| M05.40–M05.49 | Rheumatoid myopathy with rheumatoid arthritis |
| M05.50–M05.59 | Rheumatoid polyneuropathy with rheumatoid arthritis |
| M05.60–M05.69 | Rheumatoid arthritis with involvement of other organs and systems |
| M05.70–M05.79 | Rheumatoid arthritis with rheumatoid factor without organ or systems |
| M05.7A | Rheumatoid arthritis with rheumatoid factor of other specified site |
| M05.80–M05.8A | Other rheumatoid arthritis with rheumatoid factor |
| M05.9 | Rheumatoid arthritis with rheumatoid factor, unspecified |
| M06.00–M06.09 | Rheumatoid arthritis without rheumatoid factor |
| M06.0A | Rheumatoid arthritis without rheumatoid factor, other specified site |
| M06.20–M06.29 | Rheumatoid bursitis |
| M06.30–M06.39 | Rheumatoid nodule |
| M06.80–M06.8A | Other specified rheumatoid arthritis |
| M06.9 | Rheumatoid arthritis, unspecified |
| M08.20–M08.29 | Juvenile rheumatoid arthritis with systemic onset |
| M08.2A | Juvenile rheumatoid arthritis with systemic onset, other specified site |
| M08.3 | Juvenile rheumatoid polyarthritis (seronegative) |
| M08.40-M08.48 | Pauciarticular juvenile rheumatoid arthritis |
| M08.4A | Pauciarticular juvenile rheumatoid arthritis, other specified site |
| M08.80 | Other juvenile arthritis, unspecified site |
| M08.90 | Juvenile arthritis, unspecified, unspecified site |
| L40 | Psoriasis |
| L40.50-L40.59 | Arthropathic psoriasis |

## Background

Orencia (abatacept), a selective costimulation modulator, inhibits T cell (T lymphocyte) activation by binding to CD80 and CD86, thereby blocking interaction with CD28. This interaction provides a costimulatory signal necessary for full activation of T lymphocytes. Activated T lymphocytes are implicated in the pathogenesis of RA, pJIA and PsA and are found in the synovium of patients with RA, pJIA and PsA. (Orencia Prescribing Information 2023)

## Clinical Evidence

Rheumatoid arthritis (RA)

Orencia (abatacept), Remicade (infliximab), and placebo were compared in a Phase 3, randomized, double-blind trial (n = 431). Enrolled patients had an inadequate response to MTX, and background MTX was continued during the trial. Although efficacy was comparable between abatacept and infliximab after 6 months of treatment, some differences in favor of abatacept were evident after 1 year of treatment. After 1 year, the mean changes from baseline in disease activity score based on erythrocyte sedimentation rate (DAS28-ESR) were -2.88 and -2.25 in the abatacept and infliximab groups, respectively (estimate of difference, -0.62; 95% confidence interval [CI], -0.96 to -0.29). Abatacept demonstrated greater efficacy vs infliximab on some (but not all) secondary endpoints, including the proportion of patients with a good European League Against Rheumatism (EULAR) response (32.0% vs 18.5%), low disease activity score (LDAS) (35.3% vs 22.4%), ACR 20 responses (72.4% vs 55.8%), and improvements in the Medical Outcomes Study short-form-36 (SF-36) physical component summary (PCS) (difference of 1.93). Overall, abatacept had a relatively more acceptable safety and tolerability profile, with fewer serious adverse events (AEs) and discontinuations due to AEs than the infliximab group (Schiff et al 2008).

Treatment with Orencia (abatacept) was directly compared to treatment with Humira (adalimumab), when added to MTX, in a multicenter, investigator-blind, randomized controlled trial (n = 646) of RA patients with inadequate response to MTX. After 2 years, the proportions of patients achieving ACR 20 responses were comparable between abatacept and adalimumab treatment groups (59.7 and 60.1%, respectively; difference 1.8%; 95% CI, -5.6 to 9.2%). ACR 50 and ACR 70 responses were also similar between the 2 groups after 2 years of treatment. Rates of AEs were similar between treatment groups (Schiff et al 2014).

A randomized, open-label trial evaluated biologic treatments in patients with RA who had had an inadequate response to a TNF inhibitor (Gottenberg et al 2016). Patients (n = 300) were randomized to receive a second TNF inhibitor (n = 150) or a non-TNF-targeted biologic (n = 150) of the prescriber's choice. The second TNF inhibitors, in order of decreasing frequency, included Humira (adalimumab), Enbrel (etanercept), Cimzia (certolizumab), and Remicade (infliximab), and the non-TNF biologics included Actemra (tocilizumab), Rituxan (rituximab), and Orencia (abatacept). The primary endpoint was the proportion of patients with a good or moderate EULAR response at week 24, defined as a decrease in DAS28-ESR of > 1.2 points resulting in a score of ≤ 3.2.

At week 24, 52% of patients in the second anti-TNF group and 69% of patients in the non-TNF group achieved a good or moderate EULAR response (p = 0.003 or p = 0.004, depending on how missing data were handled). Secondary disease activity scores also generally supported better efficacy for the non-TNF biologics; however, HAQ scores did not differ significantly between groups. Among the non-TNF biologics, the proportion of EULAR good and moderate responders at week 24 did not significantly differ between abatacept, rituximab, and tocilizumab (67%, 61%, and 80%, respectively). There were 8 patients (5%) in the second TNF inhibitor group and 16 patients (11%) in the non-TNF biologic group that experienced serious AEs (p = 0.10), predominantly infections and cardiovascular events. There were some limitations to this trial; notably, it had an open-label design, and adherence may have differed between groups because all non-TNF biologics were given as infusions under observation and most of the TNF inhibitor drugs were self-injected by patients. The authors concluded that among patients with RA inadequately treated with TNF inhibitors, a non-TNF biologic was more effective in achieving a good or moderate disease activity response at 24 weeks; however, a second TNF inhibitor was also often effective in producing clinical improvement.

Another recent randomized trial (Manders et al 2015) evaluated the use of Ore
(rituximab) (n = 46), or a different TNF inhibitor (n = 50) in patients (n =139) with active RA despite previous TNF inhibitor treatment. Actemra (tocilizumab) was not included. In this trial, there were no significant differences with respect to DAS28, HAQ-DI, or SF-36 over the 1-year treatment period, and AEs also appeared similar. A cost-effectiveness analysis was also included in this publication, but results are not reported in this review.

A Cochrane review examined Orencia (abatacept) for the treatment of RA. ACR 50 response was not significantly different at 3 months but was significantly higher in the abatacept group at 6 and 12 months compared to placebo (relative risk [RR], 2.47; 95% CI, 2 to 3.07 and RR, 2.21; 95% CI, 1.73 to 2.82). Similar results were seen in ACR 20 and ACR 70 (Maxwell et al 2009).

Juvenile idiopathic arthritis (JIA)

In a trial of pediatric patients (6 to 17 years of age) with JIA (extended oligoarticular, polyarticular, or systemic without systemic manifestations), the patients treated with placebo had significantly more flares than the patients treated with Orencia (abatacept) ($p = 0.0003$). The time to flare was significantly different favoring abatacept ($p = 0.0002$) (Ruperto et al 2008).

Psoriatic arthritis (PsA)

Orencia (abatacept) gained FDA approval for the treatment of PsA based on 2 double-blind, placebo-controlled clinical trials in patients with an inadequate response or intolerance to DMARD therapy (Mease et al 2011, Mease et al 2017[a]). In a Phase 2 dose-finding trial (n = 170), patients received abatacept 3 mg/kg, 10 mg/kg, or 30/10 mg/kg (2 doses of 30 mg/kg then 10 mg/kg) on days 1, 15, 29 and then every 28 days (Mease et al 2011). Compared to placebo (19%), the proportion of patients achieving ACR 20 was significantly higher with abatacept 10 mg/kg (48%; $p = 0.006$) and 30/10 mg/kg (42%; $p = 0.022$) but not 3 mg/kg (33%). A Phase 3 trial (n = 424) randomized patients to abatacept 125 mg weekly or placebo (Mease et al 2017[a]). At week 24, the proportion of patients with ACR 20 response was significantly higher with abatacept (39.4%) vs placebo (22.3%; $p < 0.001$).

A network meta-analysis of 30 randomized trials (N = 10,191) compared the efficacy of infliximab, apremilast, adalimumab, tofacitinib, ustekinumab, golimumab, abatacept, secukinumab, certolizumab, brodalumab, etanercept, and ixekizumab in PsA (Qiu et al 2020). Direct and indirect comparisons were performed. In direct comparisons, most agents were better than placebo in terms of ACR 20 response rate (except adalimumab, tofacitinib, and abatacept), and no agent was significantly different from placebo in terms of serious adverse events. In the network meta-analysis, etanercept and infliximab were more effective than golimumab for ACR 20 response, and infliximab was more effective than certolizumab for PASI 75 response. Etanercept and infliximab were ranked as the most effective treatments.

A meta-analysis of 11 randomized studies (N = 5382) revealed that TNF inhibitors, IL inhibitors, and abatacept are more likely to achieve radiographic non-progression compared with placebo (Wu et al 2020). Ixekizumab and adalimumab had a similar proportion of non-progressors.

Prophylaxis for Acute Graft versus Host Disease (aGVHD)

The efficacy and safety of Orencia (abatacept) in the prophylaxis of acute GVHD was assessed in a Phase 2 trial of adults and children with hematologic malignancies undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor (Watkins et al 2021). A cohort of patients with 8/8 HLA-matched HSCT (N = 142) were randomized to blinded abatacept or placebo, each in addition to a calcineurin inhibitor (CNI) and MTX. At day 100, abatacept was associated with numeric improvements in the primary endpoint of severe (grade 3 to 4) acute GVHD (hazard ratio, 0.45; 95% CI, 0.22 to 0.90). At day 180, severe acute GVHD-free-survival (SGFS) was 93.2% for CNI/MTX plus abatacept vs 82% for CNI/MTX plus placebo ($p = 0.05$). In an open-label single-arm cohort of patients undergoing 7/8 HLA-matched HSCT (n = 43), grade 3 to 4 acute GVHD was 2.3% for CNI/MTX plus abatacept, which compared

favorably with a nonrandomized matched cohort of CNI/MTX (30.2%, p < 0.001; 58.7%, p < 0.001).

A study using data from the Center for International Blood and Marrow Transplant Research (CIBMTR) of patients 6 years and older who underwent HSCT from a 1 allele-mismatched unrelated donor demonstrated that treatment with abatacept in addition to CNI and MTX was associated with greater overall survival at day 180 post-HSCT compared with patients not treated with abatacept (98% vs 75%) (Orencia prescribing information 2021).

**Clinical Guidelines**

Rheumatoid arthritis (RA)
The America College of Rheumatology (ACR) recommends the use of conventional DMARDs, a TNF inhibitor, a non-TNF inhibitor biologic (tocilizumab, sarilumab, abatacept, or rituximab [only in patients that have had an inadequate response to TNF inhibitors or have a history of lymphoproliferative disorder]), or a JAK inhibitor (tofacitinib, baricitinib, upadacitinib). For patients who are not at target, switching to a medication in a different class is conditionally recommended over switching to a medication in the same class for patients receiving a biologic or JAK inhibitor. Biosimilars are considered equivalent to FDA-approved originator biologics. Anakinra was excluded from the ACR guideline because of its low use and lack of new data. (Fraenkel et al 2021).

EULAR guidelines for RA management were recently updated (Smolen et al 2023). EULAR recommends that therapy with DMARDs should be initiated as soon as the RA diagnosis is made with treatment aimed at reaching a target of sustained remission or low disease activity in every patient. If the treatment target is not achieved with the first conventional synthetic DMARD (csDMARD) strategy, in the absence of poor prognostic factors, other csDMARDs should be considered. If poor prognostic factors are present with csDMARD failure, a biological DMARD should be added; JAK inhibitors may be considered, but pertinent risk factors should be taken into account. In patients who cannot use csDMARDs as a comedication, IL-6 inhibitors and targeted synthetic DMARDs may have some advantages compared with other biologic DMARDs. If a biological or targeted synthetic DMARD has failed, treatment with another should be considered. If one TNF or IL-6 inhibitor therapy has failed, patients may receive an agent with another mode of action or a second TNF or IL-6 inhibitor.

The ACR released a position statement on biosimilars, which stated that the decision to substitute a biosimilar product for a reference drug should only be made by the prescriber and the prescriber. The ACR “supports the use of biosimilars to increase patients’ access to biologics” and “opposes insurer-mandated force switching to biosimilars” (ACR 2024). Similarly, the Task Force on the Use of Biosimilars to Treat Rheumatological Disorders recommends that both healthcare providers and patients should take part in the decision-making process for switching amongst biosimilars (Kay et al 2018).

EULAR has released guidelines for use of antirheumatic drugs in pregnancy, which state that etanercept and certolizumab are among possible treatment options for patients requiring therapy (Götestam Skorpen et al 2016).

The ACR/Arthritis Foundation guidelines for the management of osteoarthritis of the hand, hip, and knee strongly recommends against the use of biologics (e.g., TNF inhibitors, IL-1 receptor antagonists) for any form of osteoarthritis (Kolasinski et al 2020).

Juvenile idiopathic arthritis (JIA)
The ACR and Arthritis Foundation published a guideline for the treatment of JIA in 2019 focusing on therapy for non-systemic polyarthritis, sacroiliitis, and enthesitis. In children and adolescents with JIA and polyarthritis with moderate to high disease activity, addition of a biologic (TNF inhibitor, abatacept, or tocilizumab) is conditionally recommended. Patients with continued disease activity and primary TNF inhibitor failure are conditionally recommended to receive abatacept or tocilizumab over a second TNF inhibitor. Children and adolescents with JIA and active sacroiliitis despite treatment with NSAIDs are strongly recommended to add TNF inhibitor therapy over continuing NSAID monotherapy (*Ringold et al 2019*).

A 2021 guideline from the ACR addresses the treatment of oligoarthritis, temp A
(*Onel et al 2022*). For SJIA, an IL-1 inhibitor or IL-6 inhibitor is conditionally recommended for initial treatment, no specific agent is preferred. Monotherapy with an NSAID may also be considered for initial treatment of SJIA without macrophage activation syndrome. Systemic glucocorticoids are conditionally recommended as part of initial therapy for patients with macrophage activation syndrome. If residual arthritis is present despite these therapies, a conventional synthetic DMARD may be added or a different biologic therapy may be tried. Patients without macrophage activation syndrome who experience incomplete response or intolerance to an initial IL-1 or IL-6 inhibitor may be switched to an alternative IL-1 or IL-6 inhibitor.

Psoriatic arthritis (PsA)

Joint guidelines from the American Academy of Dermatology (AAD)/National Psoriasis Foundation (NPF) state that topical medications (e.g., corticosteroids, vitamin D analogues) are the most common agents used to treat mild to moderate PsO. They are commonly used as adjunctive therapy to phototherapy, systemic agents, and biologics (Elmets et al 2021). Phototherapy is viewed as a reasonable and effective treatment option for patients requiring more than topical medications and/or those wishing to avoid systemic medications (Elmets et al 2019). Although biologic therapies have changed the treatment landscape, non-biologic systemic agents (e.g., methotrexate) either as monotherapy or in combination with biologics, are still widely used due to benefit for widespread disease, comparatively low cost, increased availability, and ease of administration (Menter et al 2020[a]).

Joint guidelines from the AAD/NPF on the treatment of psoriasis with biologics address the effectiveness of these drugs as monotherapy or in combination to treat moderate-to-severe disease in adults. The guideline does not provide relevant ranking for preferences of individual biologics, but does recommend that etanercept, infliximab, adalimumab, ustekinumab, secukinumab, ixekizumab, brodalumab, guselkumab, risankizumab, and tildrakizumab can all be recommended as a monotherapy option for patients. Further recommendations on specific presentations of the disease, combination therapy, and dosing recommendations are included in the guidance (Menter et al 2019).

The AAD/NPF guideline on PsO in pediatric patients states that etanercept, adalimumab, and ustekinumab are effective biologic therapies for moderate to severe pediatric psoriasis. Infliximab can be recommended as monotherapy or in combination with MTX for use in pediatric patients with severe plaque or pustular psoriasis that is unresponsive to other systemic medications, rapidly progressive, unstable, and/or life threatening (Menter et al 2020[b]).

EULAR 2023 PsA guidelines recommend biologic DMARDs in patients with peripheral arthritis and an inadequate response to at least 1 synthetic DMARD, such as MTX. For patients with peripheral arthritis, an inadequate response to at least 1 synthetic DMARD, and relevant skin involvement, biologics targeting IL-12/23 or IL-17 pathways may be considered. In patients with peripheral arthritis and an inadequate response to at least one synthetic DMARD and at least one biologic DMARD, JAK inhibitors may be considered; JAK inhibitors may also be considered in patients for whom biologic DMARD therapy is not appropriate. Apremilast is considered a treatment option in patients with peripheral arthritis and an inadequate response to at least 1 synthetic DMARD, in whom biologics and JAK inhibitors are not appropriate (Gossec et al 2024).

The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) recommendations for PsA vary based on whether the arthritis is peripheral or axial and based on prior therapies, and may include DMARDS, NSAIDs, simple analgesics, a TNF inhibitor, an IL-12/23 inhibitor, an IL-23 inhibitor, an IL-17 inhibitor, a JAK inhibitor, or a PDE-4 inhibitor (Coates et al 2022[b]).
The American College of Rheumatology/National Psoriasis Foundation guideline on PsA recommends that a TNF inhibitor is preferred in treatment-naïve patients with active PsA, although an oral therapy (MTX, sulfasalazine, leflunomide, cyclosporine, or apremilast) can be a first-line option in patients without severe PsA and without severe psoriasis, or if a patient has another compelling reason to avoid a TNF inhibitor. In patients who fail oral therapy, a switch to a TNF inhibitor is preferred and placed ahead of IL-17 biologics (secukinumab, ixekizumab, brodalumab), IL-12/23 biologics (ustekinumab), abatacept, and tofacitinib (Singh et al 2019).

In 2020, the International Psoriasis Council Biosimilar Working Group published [illegible] of biosimilars in the treatment of patients with psoriasis (Cohen et al 2020). There was consensus from the Group that prescribing biosimilars to biologic-naïve patients or switching a stable patient from a reference product to a biosimilar product is appropriate if the patient and physician agree to do so. Furthermore, switching between different biosimilars should be performed with caution, until more evidence is generated supporting this practice, and multiple switches between various biosimilars and reference biologics is not the preferred option but is acceptable. Lastly, treatment switches should not occur in less than an adequate period of time (usually 6 months) from initiation of the reference product, allowing full assessment of its therapeutic effect.

Prophylaxis for Acute Graft versus Host Disease (aGVHD)

The NCCN Drugs & Biologics Compendium, NCCN recommends (2A) abatacept for the treatment of chronic graft-versus-host disease (GVHD) as additional therapy in conjunction with systemic corticosteroids following no response (steroid-refractory disease) to first-line therapy options. (NCCN 2025)

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

ORENCIA is a selective T cell costimulation modulator indicated for:

- the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA).
- the treatment of patients 2 years of age and older with moderately to severely active polyarticular juvenile idiopathic arthritis (pJIA).
- the treatment of patients 2 years of age and olderwith active psoriatic arthritis (PsA).
- the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.

## References


1. Coates LC, Soriano ER, Corp N, et al. Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA): updated treatment recommendations for psoriatic arthritis 2021. *Nat Rev Rheumatol.* 2022[b];18:465-479. doi:10.1038/s41584-022-00798-0
2. Cohen AD, Vender R, Naldi L, et al. Biosimilars for the treatment of patients with psoriasis: A consensus statement from the Biosimilar Working Group of the International Psoriasis Council. *JAAD Int*. 2020;1(2):224-230. doi:10.1016/j.jdin.2020.09.006.
3. 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. *J Am Acad Dermatol.* 2021;84(2):432-470. doi:10.1016/j.jaad.2020.07.087.
4. 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. *J Am Acad Dermatol.* 2019;81(3):775-804. doi: 10.1016/j.jaad.2019.04.042.
5. Fraenkel L, Bathon JM, England BR, et al. 2021 American College of Rheumatology Guideline for the Treatment of Rheumatoid Arthritis. *Arthritis Rheumatol*. 2021;73(7):1108-1123. doi:10.1002/art.41752.
6. Gossec L, Baraliakos X, Kerschbaumer A, et al. EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. Ann Rheum Dis. 2020;79(6):700-712. doi:10.1136/annrheumdis-2020-217159.

7. Götestam Skorpen C, Hoeltzenbein M, Tincani A, et al. The EULAR points to ugs before pregnancy, and during pregnancy and lactation. *Ann Rheum Dis*. 20
8. Gottenberg JE, Brocq O, Perdriger A, et al. Non-TNF-targeted biologic vs a second anti-TNF drug to treat rheumatoid arthritis in patients with insufficient response to a first anti-TNF drug: a randomized clinical trial. *JAMA*. 2016;316(11):1172-1180.
9. Kay J, Schoels MM, Dorner T, et al. Consensus-based recommendations for the use of biosimilars to treat rheumatological diseases. *Ann Rheum Dis*. 2018;77(2):165-174. doi: 10.1136/annrheumdis-2017-211937.
10. Kolasinski SL, Neogi T, Hochberg MC, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the management of osteoarthritis of the hand, hip, and knee. *Arthritis Rheumatol*. 2020;72(2):220-233. doi:10.1002/art.41142.
11. Manders SH, Kievit W, Adang E, et al. Cost-effectiveness of abatacept, rituximab, and TNFi treatment after previous failure with TNFi treatment in rheumatoid arthritis: a pragmatic multi-centre randomised trial. *Arthritis Research & Therapy*. 2015;17:134.
12. Maxwell L, Singh JA. Abatacept for rheumatoid arthritis. *Cochrane Database Syst Rev*. 2009;(4):CD007277.
13. Mease P, Genovese MC, Gladstein G, et al. Abatacept in the treatment of patients with psoriatic arthritis: results of a six-month, multicenter, randomized, double-blind, placebo-controlled, phase II trial. *Arthritis Rheum*. 2011;63(4):939-948.
14. Mease PJ, Gottlieb AB, van der Heijde D, et al. Efficacy and safety of abatacept, a T-cell modulator, in a randomised, double-blind, placebo-controlled, phase III study in psoriatic arthritis. *Ann Rheum Dis*. 2017[a];76(9):1550-1558.
15. Menter A, Cordoro KM, Davis DMR, et al. Joint American Academy of Dermatology-National Psoriasis Foundation guidelines of care for the management and treatment of psoriasis in pediatric patients. *J Am Acad Dermatol*. 2020[b];82(1):161-201. doi:10.1016/j.jaad.2019.08.049.
16. 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[a];82(6):1445-1486. doi:10.1016/j.jaad.2020.02.044.
17. 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.
18. The NCCN Drugs & Biologics Compendium® (NCCN Compendium®). Available at www.nccn.org. Accessed on March 20, 2025.
19. Onel KB, Horton DB, Lovell DJ, et al. 2021 American College of Rheumatology guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for oligoarthritis, temporomandibular joint arthritis, and systemic juvenile idiopathic arthritis. *Arthritis Rheumatol*. 2022;74(4):553-569. doi:10.1002/art.42037.
20. Orencia [prescribing information]. Princeton, NJ: Bristol-Myers Squibb Company; December 2023.
21. Ringold S, Angeles-Han ST, Beukelman T, et al. 2019 American College of Rheumatology/Arthritis Foundation guideline for the treatment of juvenile idiopathic arthritis: therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis. *Arthritis Care Res (Hoboken).* 2019;71(6):717-734. doi: 10.1002/acr.23870.
22. Ruperto N, Lovell DJ, Quartier P, et al; Pediatric Rheumatology International Trials Organization; Pediatric Rheumatology Collaborative Study Group. Abatacept in children with juvenile idiopathic arthritis: a randomized, double-blind, placebo-controlled withdrawal trial. *Lancet.* 2008;372(9636):383-91.
23. Qiu M, Xu Z, Gao W, et al. Fourteen small molecule and biological agents for psoriatic arthritis: A network meta-analysis of randomized controlled trials. *Medicine (Baltimore).* 2020;99(31):e21447. doi:10.1097/MD.0000000000021447.
24. Schiff M, Keiserman M, Codding C, et al. Efficacy and safety of abatacept or infliximab vs placebo in ATTEST: a phase III, multi-centre, randomised, double-blind, placebo-controlled study in patients with rheumatoid arthritis and an inadequate response to methotrexate. *Ann Rheum Dis.* 2008;67:1096-1103.

25. Schiff M, Weinblatt ME, Valente R, et al. Head-to-head comparison of subc for rheumatoid arthritis: two-year efficacy and safety findings from AMPLE tri
26. Singh JA, Guyatt G, Ogdie A, et al. Special Article: 2018 American College of Rheumatology/National Psoriasis Foundation guideline for the treatment of psoriatic arthritis. *Arthritis Rheumatol*. 2019;71(1):5-32. doi: 10.1002/art.40726.
27. Smolen JS, Landewe RBM, Bergstra SA, et al. EULAR recommendations for the management of rheumatoid arthritis with synthetic and biological disease-modifying antirheumatic drugs: 2022 update. *Ann Rheum Dis*. 2023;82:3-18. doi:10.1136/ard-2022-223356
28. Watkins B, Qayed M, McCracken C, et al. Phase II trial of costimulation blockade with abatacept for prevention of acute GVHD. *J Clin Oncol.* 2021;39(17):1865-1877. doi:10.1200/JCO.20.01086.
29. Wu D, Li C, Zhang S, et al. Effect of biologics on radiographic progression of peripheral joint in patients with psoriatic arthritis: meta-analysis. *Rheumatology (Oxford).* 2020;59(11):3172-3180. doi:10.1093/rheumatology/keaa313.
30. Wu D, Yue J, Tam LS. Efficacy and safety of biologics targeting interleukin-6, -12/23, and -17 pathways for peripheral psoriatic arthritis: a network meta-analysis. *Rheumatology.* 2018;57(3):563-571 doi: 10.1093/rheumatology/kex452.

## Policy History/Revision Information

| Date | Summary of Changes |
|---|---|
| 11/16/2023 | Approved by OptumRx P&T Committee |
| 04/17/2024 | Annual review. Updated References. |
| 04/16/2025 | Annual review. Updated reauth verbiage, clinical guidelines & references. |

## Instructions for Use

This Medical Benefit Drug Policy provides assistance in interpreting standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. The insurance reserves the right to modify its Policies and Guidelines as necessary. This Medical Benefit Drug Policy is provided for informational purposes. It does not constitute medical advice.

OptumRx may also use tools developed by third parties to assist us in administering health benefits. OptumRx Medical Benefit Drug Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

## Archived Policy Versions (Internal Only)

| Effective Date | Policy Number | Policy Title |
|---|---|---|
| mm/dd/yyyy – mm/dd/yyyy | ###### | Title of Policy Hyperlinked to KL or Other Internal Location |

# Nondiscrimination & Language Acce

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federa[illegible]te on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

*You* can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

*You* can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

## Language Assistance Services

**Albanian**: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

**Arabic** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

**French**: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

**German**: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

**Hindi**: _यान द_: य_द आप िहंदी बोलते ह_ तो आपके िलए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

**Hmong**: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

**Korean**: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

**Polish**: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

**Russian**: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

**Spanish**: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

**Tagalog**: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

**Traditional Chinese**: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

**Vietnamese**: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

**Pennsylvania Dutch**: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

**Lao**: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).

# Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

*You* can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

*You* can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

## Language Assistance Services

**Albanian**: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

**Arabic** تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

**French**: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

**German**: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

**Hindi**: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

**Hmong**: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

**Korean**: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

**Polish**: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

**Russian**: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

**Spanish**: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

**Tagalog**: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

**Traditional Chinese**: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

**Vietnamese**: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

**Pennsylvania Dutch**: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

**Lao**: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).